UNIVERSITY OF LIVERPOOL

Clinical Directorate Clinical Research Governance Team

Statement of Policy

Sponsorship of Research

POL001

Author Karen Jennings-Wilding	**Date of Approval** 26th October 2023
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As of the issue date of this Policy the Single Point of Access for Research and Knowledge (SPARK) is in the process of changing name to Joint Research Office (JRO). References to SPARK in this SOP will refer to JRO when the name is officially changed, and will be updated at the next review.

Contents

1. Introduction

This document outlines the University's Sponsorship of Research Policy. It complies with, and is reflective of, the regulatory framework for:

- Clinical and non-clinical research undertaken with, or impacting on, the NHS (as governed by the UK Policy Framework for Health and Social Care Research, herein the UK Policy Framework);
- Clinical Trials of Investigational Medicinal Products (as governed by the Medicines for Human Use (Clinical Trials) Regulations 2004) and the Clinical Trials of Medical Devices (as governed by the Medical Devices Directive 2002) (herein the Regulations).

The University's Sponsorship of Research Policy provides an environment within which compliance with the UK Policy Framework and the Regulations can be achieved across all of our research activities, and its standards and principles should be applied to healthcare research that falls within and out with of the UK Policy Framework and the Regulations, to ensure a consistent approach.

A sponsor is defined for the purposes of this Policy as the body that guarantees and oversees a research project or clinical trial, ensuring that there are proper arrangements in place to initiate, manage, monitor and finance a study. A detailed definition of the role of sponsor under the UK Policy Framework and under the Regulations is provided at Appendices 2 and 3 to this Policy.

The Policy should be read in conjunction with the Glossary of Terms, outlined in Section 6 of the document.

2. Administration of the Sponsorship Process

The role of Sponsor is facilitated by the Clinical Research Governance Team, part of the Clinical Directorate within the Faculty of Health and Life Sciences.

All enquiries relating to sponsorship of research must, in the first instance, be directed to the Sponsorship Team via sponsor@liverpool.ac.uk.

The Sponsorship Team acts as the secretariat to the Liverpool Health Partners (LHP) Single Point of Access for Research and Knowledge (SPARK) Sponsorship Committee or Non-Interventional Sponsorship Sub-Committee (NISSC). Each committee is responsible for reviewing and approving applications for sponsorship on behalf of the University. The schedule of meeting dates and deadlines, Terms of Reference and Membership can be requested from the Clinical Research Governance Team.

Support for the necessary contractual arrangements, as outlined on a study-by-study basis in Appendix 1, is provided by the Research Contracts Team, part of Legal & Compliance.

3. Studies Requiring Sponsorship

The University requires Sponsorship be obtained for the below types of research;

- Involvement of patients and users of the NHS including use of their data, tissue or other bodily material;
- Involvement of relatives or carers of NHS patients;
- Use of NHS premises or resources,
- Recruitment of NHS Staff as participants;
- Any Clinical Trial of Investigational Medicinal Product (CTIMP), regardless of the proposed participant population;
- Human Health related based Studies taking place at international sites;
- Recruitment of participants who lack capacity to consent;
- Research involving participant exposure to radiation;
- Research involving identification and recruitment of participants via private healthcare providers, including from Care Homes and palliative care facilities.

The University may require Sponsorship be obtained for research that may not be listed in this policy if there is deemed to be a risk to the institution and as such require a higher level of oversight. Any such decision will be made between the Senior Clinical Research Governance Manager and the Chair of the SPARK Sponsorship Committee.

Table 1 at Appendix 1 provides examples of the types of study that may require sponsorship. It provides a definition of the type of sponsorship that may be required, the regulatory framework that would apply to that sponsorship decision, and the legal arrangements that would be required to affect the Sponsorship. The table is provided as a guide to potential applications but is not meant to be an exhaustive list. Any queries should be directed to the Sponsorship Team via sponsor@liverpool.ac.uk.

4. Principles of University Sponsorship

In making a Sponsorship decision, the University will be guided by the following principles:

4.1 Overarching Principles

i. Sponsorship cannot be presumed and sponsorship approval must be obtained prior to submission for NHS Research Ethics Committee (REC) or regulatory authority review. This is gained through application to the SPARK Sponsorship Committee or NISSC. The University will consider undertaking the role of sponsor for the following:

   a. Research being undertaken by employees of the University

   b. University Student research projects (where the academic supervisor is a University employee)

   c. Submissions from Investigators external to University will be considered on a case by case basis, but it is expected the employing organisation will undertake the role of Sponsor.

ii. Investigators should not identify the University as sponsor or co-sponsor until formal approval is received from the relevant Committee;

iii. Where required by a funder a Sponsorship in Principle letter can be requested to enable the funding application to made. This letter will state that the study must be submitted for a full Sponsorship Review after confirmation of the funding award;

iv. In exceptional circumstances, an Intention to Sponsor letter may be provided to enable applications to proceed to Regulatory and Ethics submission prior to full Sponsorship Review taking place. This decision will be made at the discretion of the Chair of the SPARK Sponsorship Committee or NISSC following receipt of the sponsorship application and a letter detailing the extenuating circumstances as to why it has to be submitted to REC before Sponsorship is applied for;

v. In the case of research projects being under taken by a student as part/fulfilment of an academic qualification, the application for sponsorship should be made in the name of the student's University-employed supervisor, with that supervisor taking on the responsibility for and being named as the Chief Investigator;

vi. The University does not permit its members of staff or students to assume the role of sponsor on a personal basis;

vii. The University will not enter into joint sponsorship arrangements (as defined by the Regulations);

viii. Requests for sponsorship or co-sponsorship should be submitted on the Sponsorship Application Form, and submitted, along with appropriate study documentation to the Sponsorship Team. The form must be requested from the Sponsorship Team or accessed via the LHP SPARK Research Sponsorship website to ensure that the correct version is completed.

4.2 Responsibilities of the Chief Investigator

i. The University requires all its employees who act as Chief Investigator (CI) for a research project to be fully aware of their responsibilities under the UK Policy Framework and the Regulations.

ii. At the stage of the submission of the Sponsorship application the Chief Investigator will also be expected to provide evidence of the following;

- Independent peer review which confirms the project is of high scientific quality;
- Adequate resources and support are available to deliver the proposed research;
- Confirmation that adequate measures are in place for the management of the project;

iii. Following Sponsorship Approval and prior to the study opening to recruitment the following will be required from the CI;

- The appropriate approvals from REC, NHS Trust (or other relevant health or social care provider) and any other regulatory body are in place;
- Completion of required agreements with research sites and collaborators;
- Evidence of appropriate training for the CI and key study team members;

- Other supporting documents as requested by the Sponsorship Team.

iv. The Chief Investigator will be expected to provide information to the University and any co-sponsoring organisation when requested, and to co-operate with any audit or inspection (e.g. by the University, a co-sponsor, or regulatory authorities such as the Medicines & Healthcare products Regulatory Agency (MHRA) at any time during or following project completion.

4.3 Research carried out within the UK: Broad Principles

i. All research being carried out by a University employee that requires sponsorship under the UK Policy Framework or the Regulations should be referred to the Clinical Research Governance Team. Although the University would normally expect to assume the role of sponsor or co-sponsor for research projects carried out by its employees, it will consider the appropriateness of an alternative organisation assuming this role. For example, the University would normally expect commercially-initiated studies to be sponsored by the commercial funder;

ii. If a suitable alternative organisation, such as an NHS Trust, a charitable funding organisation, a social care provider, or a commercial company, agrees to take on the full role of sponsor for a research project led by a University employee, the Chief Investigator must ensure that all appropriate arrangements and agreements are in place for the delegation of functions and responsibilities, as well as any payments that are required;

iii. The specific arrangements for Sponsorship and management of Clinical Trials of Investigational Medicinal Products (CTIMPs)s are covered in POL002[1].

4.4 Research delivered outside of the UK: Broad Principles

i. If any University Sponsored research study or CTIMP involves, or has the potential to involve overseas sites, it is the responsibility of the Chief Investigator to inform the Sponsorship Team at the earliest opportunity in order that the appropriate insurance costs can be established by the University and to ensure that the Chief Investigator has identified sources of funding to meet these costs and, to check that governance requirements can be met for these sites.

ii. Although the UK Policy Framework definition of Sponsor only applies to UK based research involving the NHS, the University also require that Sponsorship is obtained for research being carried out internationally which involves healthcare organisations/structures. This is to ensure the University has oversight of research being carried out and also to ensure that appropriate insurance is obtained.

iii. CTIMPs with trial sites outside of the UK but within the European Economic Area (EEA)/EU would require sponsorship in accordance with the Clinical Trials Regulation (Regulation (EU) No 536/2014. If the University is acting as UK Sponsor, then a legal representative in a EEA

[1] Policy for Clinical Trials of Investigational Medicinal Products Sponsored by the University

country on the approved country list must be appointed. It is imperative that the involvement of EU countries in CTIMPs is highlighted as soon as possible.

iv. CTIMP sites outside the EU are not covered by the Clinical Trials Regulation (Regulation (EU) No 536/2014) and therefore do not require formal sponsorship under the Regulations. However, the University also require that Sponsorship is obtained for all research being carried out internationally which involves healthcare organisations/structures. This process ensures that all healthcare-based research being carried out by the University is conducted to the same standards and principles of Good Clinical Practice and best practice are upheld. This process also enables the University to have oversight of all healthcare-based research being carried out and also to ensure that appropriate insurance is obtained.

4.5 Insurance

i. Insurance is required to cover all of the University's liabilities in relation to its research activity. The University has insurance policies in place to cover Professional Indemnity, Clinical Trials Insurance and Public Liability Insurance, which together provide cover for much of the University's research portfolio. However, there are some notable exceptions to this, where specific projects may need to be referred to the University's insurers to confirm cover, or further, where additional insurance may be required. This includes, for example, research taking place in overseas sites where local legislation may prevent the use of our UK policy and require locally sourced insurance cover, or relating to vulnerable groups of patients. It is essential that any additional insurance costs are established and that the Chief Investigator has identified funding to meet these costs.

ii. This should occur before funding applications are made to enable these costs to be incorporated into the application. The University will not normally pay for additional insurance costs and research may not be able to proceed unless alternative funding for this insurance is found. It is the responsibility of the Chief Investigator to ensure that there is appropriate funding to cover all of the costs of the research including insurance costs. Therefore, Chief Investigators are advised to contact the Sponsorship Team via sponsor@liverpool.ac.uk at the earliest opportunity to clarify the insurance arrangements for a particular trial.

5. Glossary of Terms

Term	Definition
Chief Investigator (CI)	Under the Clinical Trials Regulations chief investigator means - a) in relation to a clinical trial conducted at a single trial site, the investigator for that site, or b) in relation to a clinical trial conducted at more than one trial site, the authorised health care professional, whether or not he is an investigator at any particular site, who takes primary responsibility for the conduct of the trial; Under the UK Policy Framework, the chief investigator is the overall lead

Term	Definition
	researcher for a research project. In addition to their responsibilities if they are members of a research team, chief investigators are responsible for the overall conduct of a research project.
Clinical Trial of an Investigational Medicinal Product (CTIMP)	Any investigation in human subjects, other than a non-interventional trial, intended: • to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products; • to identify any adverse reactions to one or more such products; or • to study absorption, distribution, metabolism and excretion of one or more such products; • with the objective of ascertaining the safety or efficacy of those products.
Co-Sponsorship	A sponsorship arrangement whereby two or more organisations agree to act as sponsors, allocating responsibility between them for carrying out the functions of the sponsor.
Clinical Trials Regulation (Regulation (EU) No 536/2014	The Clinical Trials Regulation harmonises the processes for assessment and supervision of clinical trials throughout the EU. The evaluation, authorisation and supervision of clinical trials are the responsibilities of EU Member States and European Economic Area (EEA) countries.
ICH GCP	The International Convention on Harmonisation of Good Clinical Practice
Investigational Medicinal Product (IMP)	A pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be used, as a reference in a clinical trial, and 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.
MHRA	Medicines and Healthcare products Regulatory Agency
mNCA	The UK wide model Non-Commercial Agreement (mNCA) template is structured to meet the requirements of non-commercial sponsors and the NHS/HSC (or other) bodies undertaking the research. This agreement has been developed as a single UK-wide agreement template, meaning that it can be used irrespective of where the sponsor and research site are established. It is designed to be used without

Term	Definition
	modification or negotiation.
Principal Investigator (PI)	The clinician responsible for a team of investigators conducting a study at a particular site. In multi-site studies all sites will require a PI.
UK Policy Framework	UK Policy Framework for Health and Social Care Research
the Regulations	The Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument 2004 No. 1031)
Sponsor	The sponsor in this context is the body which guarantees or oversees the research. The UK Policy Framework defines the sponsor as "the 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 Regulations define the sponsor as "an individual, company, institution or organisation, which takes responsibility for the initiation, management and/or financing of a clinical trial.

6. Appendix 1- Sponsorship Arrangements for Specific Study Types

Please note that although this table is broad, it should not be thought of as comprehensive and investigators are encouraged to liaise with the Sponsorship team if they have any queries about the type of study they are developing

Type of Study	Participants	Location of Site(s)	Type of Sponsorship Required	Regulatory Framework (where applicable)
Research initiated by industry	Any	Any	By the Funder	Any relevant
CTIMP	NHS Patients / Healthy Volunteers	UK	UoL Sole Sponsorship as standard. Co-Sponsorship considered on a case by case basis.	Medicines for Human Use (Clinical Trials) Regulations 2004 UK Policy Framework for Health and Social Care Research
CTIMP	Patients / Healthy Volunteers	UK including EU site(s)	Sponsorship required for all research countries. UoL Sole Sponsorship as standard. Co-Sponsorship considered on a case by case basis.	Medicines for Human Use (Clinical Trials) Regulations 2004 (UK sites) Clinical Trials Regulation (Regulation (EU) No 536/2014) (EU sites)

Type of Study	Participants	Location of Site(s)	Type of Sponsorship Required	Regulatory Framework (where applicable)
CTIMP	Patients	UK including International site(s) outside of EU	Sponsorship required for all research countries. UoL Sole Sponsorship as standard. Co-Sponsorship considered on a case by case basis.	Medicines for Human Use (Clinical Trials) Regulations 2004 (UK sites) Governing policy for research in country where research is taking place.
CTIMP	Patients	International only	Sponsorship required for all research countries. UoL Sole Sponsorship as standard. Co-Sponsorship considered on a case by case basis.	Governing policy for research in country where research is taking place.
Clinical Investigation of a medical device	NHS Patients/ Healthy Volunteers	UK	UoL Sole Sponsorship as standard. Co-Sponsorship considered on a case by case basis.	The Medical Devices Regulations 2002 UK Policy Framework for Health and Social Care Research
Performance Evaluation of an in vitro diagnostic device	NHS Patients	UK	UoL Sole Sponsorship as standard.	UK Policy Framework for Health and Social Care Research
Human tissue [newly obtained, identifiable or obtained from surplus]	NHS Patients	UK	Sole Sponsorship by UoL	UK Policy Framework for Health and Social Care Research Human Tissue Act 2004

Type of Study	Participants	Location of Site(s)	Type of Sponsorship Required	Regulatory Framework (where applicable)
Human tissue samples [anonymous to investigator]	NHS Patients	UK	Sole Sponsorship by UoL	UK Policy Framework for Health and Social Care Research Human Tissue Act 2004
Questionnaire/ Interview-Based studies	NHS Patients / Users of Social Care Services	UK	Sole Sponsorship by UoL	UK Policy Framework for Health and Social Care Research
Any	Recruited via a Private Health provider, care home or palliative care facility	UK	Sole Sponsorship by UoL	N/A

7. Appendix 2 - Definition and Description of Sponsor Responsibilities Under the UK Policy Framework

9.10. The sponsor is the 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. All health and social care research has a sponsor. 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 employer or funder is not automatically the sponsor; they explicitly accept the responsibilities of being the sponsor). The 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) (For educational research, the scientific validity and quality may be established by the chief investigator (i.e. the supervisor) at a level appropriate to the nature of the course), 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 (For educational research, registration, accessibility of data and tissues, and dissemination may be limited to institutional arrangements);

f) ensuring that, where expected or required, the research has approval from a research ethics committee (Whether outright or following a provisional opinion, resubmission or appeal) 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.

9.11. Sponsors of clinical trials of investigational medicinal products have particular legal duties – see the HRA Planning and Improving Research page for details.

9.12. Universities and colleges should accept the role of 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. Sponsors of educational research should ensure that supervisors can and do carry out the activities involved in fulfilling this role. Where the academic supervisor cannot adequately satisfy the sponsor's oversight responsibilities due to location or expertise, the sponsor should agree co-supervision arrangements with a local care practitioner.

8. Appendix 3 - Definition and Responsibilities of the Sponsor under the Medicines for Human Use (Clinical Trials) Regulations 2004

Definition of Sponsor Under the Regulations

The Regulations define the sponsor as

"an individual, company, institution or organisation, which takes responsibility for the initiation, management and/or financing of a clinical trial".*

*please note that the University does not allow individuals to take on the responsibility of Sponsor.

Under the Regulations, it is a criminal offence to conduct a clinical trial of an investigational medicinal product (CTIMP) without a sponsor. For trials undertaken in or involving the NHS, the requirements of the Regulations need to be seen alongside the responsibilities laid out in the UK Policy Framework, which continue to apply.

The legal obligations relating to sponsorship which are detailed in the Regulations are grouped into several categories, as detailed below.

i. Part 3: Authorisation and Ethics Committee Opinion

- Request clinical trial authorisation (CTA), amend the request
- Undertake to allow inspection of sponsor's premises
- Give notice of amendments to CTA, make representations and amendments
- Give notice of amendments to the protocol
- Give notice a trial has ended

ii. Part 4: Good Clinical Practice (GCP) and Conduct

- Put and keep in place arrangements to adhere to GCP
- Ensure Investigational Medicinal Products (IMPs) are made available to subjects free of charge
- Take appropriate urgent safety measures (if no other person is specified to do so)

iii. Part 5: Pharmacovigilance

- Ensure recording and prompt reporting of suspected unexpected serious adverse reactions (SUSARs)
- Ensure investigators are informed of SUSARs
- Ensure all SUSARs including those in third countries are entered into the European database
- Provide annual list of suspected adverse reactions and a safety report

- Keep records of all adverse events reported by investigators

iv. Part 6: Manufacture and Importation of Investigational Medicinal Products

- Ensure that no person manufactures, assembles or imports any Investigational Medicinal Product except in accordance with authorisation granted by licensing agency
- Make any required applications for manufacturing authorisation
- Ensure that a Qualified Person is in place to take responsibility for the Investigational Medicinal Product

v. Part 7: Labelling of Investigational Medicinal Product

- Ensure labelling and dispensing of Investigational Medicinal Products in accordance with regulations