Clinical Directorate Clinical Research Governance Team

Standard Operating Procedure

Production and Management of Contracts for University Sponsored Clinical Research Activity

SOP016

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Approved on behalf of ratifying committee	**Date of Approval**
Professor Tony Marson (Chair of LHP SPARK Committee)	15th November 2023

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1. Introduction

It is the intention of this SOP to determine the contractual arrangements which may be needed and the steps required to implement them, where the University of Liverpool is to act as the Sponsor of clinical research. For this SOP the definition of clinical research will comply with the requirements for Sponsorship as laid out in SOP004[1];

- 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 and/or resources;
- 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

The University of Liverpool must comply with all applicable regulations and legislation when undertaking clinical research activities, such as the Medicines for Human Use (Clinical Trials) Regulations 2004 (the Regulations) and the UK Policy Framework for Health and Social Care Research, and it seeks to achieve such compliance through the following procedures.

2. Scope of Procedure

This SOP details the processes to be followed where a contractual relationship with a third party is required to facilitate Clinical Research Activities.

3. Who

The University recognises that this SOP is most applicable to the following departments:

- Clinical Directorate Clinical Research Governance team (CRGT);
- Legal and Governance Research Contracts team (RCT);
- Liverpool Clinical Trials Centre (LCTC)
- GCP Laboratories

This list is not exhaustive and Clinical Research Governance Team will ensure this SOP is made easily accessible to those departments and individuals who are likely to participate in clinical research via the Clinical Research Governance internal website. Upon receiving Sponsorship Approval from the University, investigators will be directed to this website.

[1] Sponsorship Application and Approval Process

4. When

This SOP will apply where a contractual relationship with a third party is required to implement or to further the undertaking of a clinical research activity. Sponsorship often requires a variety of agreements to address different aspects of a clinical research activity. Examples include, but are not limited to:

Agreement Type	Purpose	Template Controlled by	Responsible Department
Funding Agreements	The overall source of funding. Such potential funders include, but aren't limited to, the Government, industry, research councils, charities and the EU.	Funder	Research Support Office and Research Contracts Team
Co-Sponsorship Agreement	Where the University Co-Sponsors a study with a NHS trust in the UK or a third party outside of the UK, this agreement will define the statutory obligation of both parties and any division of those responsibilities. If the NHS Co-Sponsor is also the lead NHS Trust the Research Site Agreement will be included in this agreement.	Co-Sponsorship from Research Contracts Team Co-Sponsorship Division of Responsibilities template (TEM025) from Clinical Research Governance Team	Clinical Research Governance Team and Research Contracts Team
Medical Intervention Supply Agreement	The agreement dealing with the production, packaging, labelling and distribution of an IMP, as appropriate, as well as any additional money.	Supplier	Research Contracts Team
Collaboration Agreement	This flows the terms of the Funding Agreement down to collaborators. This will supplement the co-sponsorship agreement by determining (amongst other things): the governance and management structure of the study; the distribution of funds; how the study is to be monitored; the procedure for producing publications; the liability of the collaborators to each other and their obligations of indemnity; the ownership, protection and management of any intellectual property produced from the study.	Research Contracts Team	Research Support Office and Research Contracts Team

Agreement Type	Purpose	Template Controlled by	Responsible Department
Subcontract	If an external organisation is being contracted to provide services for the delivery of the clinical research activity (other than for Medical Intervention Supply), but they are not named on the grant application a subcontract will be required to define the terms of their engagement and outline the method of payment.	Research Contracts Team	Research Support Office and Research Contracts Team
Model Non-Commercial Agreement (mNCA)	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 modification or negotiation. The mNCA has been developed for a range of interventional research scenarios, including clinical trials, medical device studies, research using patient data and research using human tissue.	Health Research Authority (HRA) Localised copy controlled by Clinical Research Governance Team	Clinical Research Governance Team for unmodified agreements. Research Contracts Team for modified agreements
Material Transfer Agreement	To cover the transfer of relevant human material, between the parties.	Research Contracts Team	Research Contracts Team
Data Transfer Agreements including Data Processing Agreements, Joint Controller Agreements, Data Sharing Agreements and International Data Agreements	To cover the transfer of data between the parties.	Research Contracts Team	Research Contracts Team
Confidentiality Agreements	To impose obligation of confidentiality on parties. Often used in the planning stage or when third parties who are not covered by	Research Contracts Team	Research Contracts Team

Agreement Type	Purpose	Template Controlled by	Responsible Department
	any other agreement involves in a project.		
Organisation Information Document (OID)	The Organisation Information Document should be used to provide information on participating NHS/HSC organisations in the UK. For non-commercial studies it should be accompanied by a completed Schedule of Events. The two documents allow the sponsor to make clear what activities will be undertaken locally and the cost type for each activity.	Health Research Authority (HRA)	Clinical Research Governance Team for unmodified OID. Research Contracts Team for modified OID.
CI Agreement	Binding the Chief Investigator's employer contractually to their responsibilities in a Study. Used when the University are the Sponsor but the Chief Investigator is employed by an external party.	Research Contracts Team	Research Contracts Team
Quality/Technical Agreement	Entered into alongside Medical Intervention Supply Agreement. Required by the Regulatory Authority for CTIMPS. Sets out the technical responsibility of the company who are delivering the product.	Research Contracts Team	Research Contracts Team
International Research Site Agreement	Bespoke agreement with site located outside of the UK. Ensuring compliance with protocol, data protection and the transfer of funds (If applicable).	Research Contracts Team	Research Contracts Team

Where the University is the sole Sponsor of a study which is being managed by the LCTC, then the University will implement an Internal Delegation Plan[2]. It is the intention of the Internal Delegation Plan to clarify the roles that will be undertaken within the University for the effective management and conduct of the CTIMP. The Internal Delegation Plan may also be implemented for use in Non-CTU managed studies to lay out the functions to be undertaken by a CI and their study team[3]. An External CTU Communication Plan[4] will be implemented where a CTIMP is being managed by a CTU external to the University.

[2] TEM033 LCTC Sole Sponsorship Internal Delegation Plan
[3] TEM022 Non-CTU Sole Sponsorship Internal Delegation Plan
[4] TEM034 External CTU Communication plan

5. Identification of required Contracts and Referral process

A member of the Research Contracts Team will be appointed on both the Liverpool Health Partners (LHP) Single Point Of Access To Research And Knowledge (SPARK) Sponsorship Committee and Non-Interventional Sponsorship Sub-Committee (NISSC) and provide comments on each application in turn.

Where it is identified that contracts are required the Sponsor Responsible Officer will notify the CI and/or study/trial team of the contracts required. The CI is then responsible for requesting the contract from the Research Contracts Team and provide required documentation to the allocated Contracts Officer. The Sponsor Responsible Officer will ensure completion of required contracts via the Sponsor Permission to Proceed process.

The Research Contracts Team are responsible for drafting, negotiating and signing contracts with external parties required for research, unless formally delegated via the Delegation of Authority.

The Clinical Research Governance Team (specifically the Senior Clinical Research Governance Manager) will retain responsibility for the drafting, completion and signature of the Organisation Information Document (OID) and Model Non-Commercial Agreement (mNCA), and such agreements do not require referral. Although the mNCA is designed to be used without modification or negotiation, there may be extenuating circumstances where modifications are required. In such cases referral to the Research Contracts Team must be made to ensure suitability of the changes.

Signatures of agreements will be initiated using electronic signature platforms such as DocuSign, Adobe Sign or Box. Fully executed versions of all agreements will be provided to the CI/Clinical Trials Unit or Study Team for inclusion in the Trial or Study Master File. Agreements also need to the provided to the relevant Research Support Officer for upload onto IRIS (Integrated Research Information System) and CACTUS – the University Contracts and Agreements System.

6. Amendments to Contracts

The Research Contracts team shall be responsible for drafting, reviewing, negotiating and authorising any necessary amendments to existing contracts.

The notification of the need for any such amendments and the referral of the agreement from the CRGT will be made via email as outline above.

If the agreement includes funding and the amendment is initiated by the Research Support Office the referral will be made via CACTUS.

7. Roles and Responsibilities

The CI, with support from the Research Contracts Team and Sponsor, is ultimately responsible for ensuring all appropriate contracts are in place before the study opens to recruitment. The functions of completing the contracts process are detailed below;

Chief Investigator

- Applying for appropriate Sponsorship – See SOP004 for more information;

- Inform the Sponsor(s) of proposed sites and collaborators for the study;
- Requesting required contracts from the Research Contracts Team
- Ensuring all required agreements are executed before commencement of the study, and obtaining advice on these matters;
- Ensuring that additional agreements are in place, as needed and as defined by the Responsible Sponsorship Officer, during the lifespan of the project, and obtaining advice on these matters;
- Where the study is not being managed by a CTU the CI will ensure that trial specific template and fully executed agreements are held in the TMF or Study Master File.

Responsible Sponsorship Officer

- Completion of the Delegation of Responsibilities for Co-Sponsorship Agreements;
- Review the Division of Responsibilities for mNCAs;
- Hold, maintain, release, review and approve the template Internal Delegation Plan and External Communication Plan as required;
- Provide copies of fully executed agreements to the Research Support Office for upload to IRIS and CACTUS;
- Provide advice to the CI and trial team regarding the contracts required to be completed as part of the Sponsor Permission to Proceed process.

Senior Clinical Research Governance Manager

- Review and approve unmodified template mNCAs and OIDs;
- Where changes are required to template agreements, provide these for review to the RCT;
- Complete a quality control check against the agreed template agreement following review by external signatories to ensure any and all changes are identified;
- Coordinate review and signature by sites/collaborators;
- Review and approve LCTC Internal Delegation Plans, Non-CTU Internal Delegation Plans and External CTU Communication plans;

Research Contracts Team

- Maintain template agreements as detailed in Section 4 Support with the drafting, negotiation, review and signature of appropriate agreements required to support the undertaking of clinical research;
- Review and approve post signature amendments to agreements (where this has not been formally delegated);

- Provide advice on legal and contractual issues at LHP SPARK Sponsorship Committee and NISSC and on an ad-hoc where required.

Institute Head of Operations

- Review and approve standard, unmodified material transfer agreements and Confidentiality Disclosure Agreements.

Liverpool Clinical Trials Centre – Trial Coordinator

- Review and approve unmodified template mNCAs as delegated on Trial Delegation Log;
- Complete a quality control check against the agreed template agreement following review by external signatories to ensure any and all changes are identified;
- Where changes are required to template agreements, provide these for review to the RCT;
- Complete template agreements with study specific details;
- Coordinate review and signature by sites/collaborators;
- Hold trial specific template agreements in the TMF;
- Provide copies of fully executed agreements to the Research Support Office for upload to IRIS and CACTUS.

GCP Laboratories – Facility Director or Manager

- Complete a quality control check against the agreed template agreement following review by external signatories to ensure any and all changes are identified;
- Where changes are required to template agreements, provide these for review to the RCT;
- Complete template agreements with study and laboratory specific details;
- Hold trial specific template and fully executed agreements in the Laboratories Quality System.

8. Abbreviations

CI	Chief Investigator
CIMD	Clinical Investigation of Medicinal Device
CRGT	Clinical Research Governance team
CTIMP	Clinical Trial of Investigational Medicinal Product
CTU	Clinical Trials Unit
IDP	Internal Delegation Plan

IMP	Investigational Medicinal Product
LCTC	Liverpool Clinical Trials Centre
mNCA	Model Non-Commercial Agreement
PI	Principle Investigator
RCT	Research Contracts Team
SOP	Standard Operating Procedure
University	The University of Liverpool

9. Associated Documents and References

UK Policy Framework for Health and Social Care Research

The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004 No. 1031)

IRAS Template Contracts and study agreements

HRA Guidance for Model Agreements

University of Liverpool SOPs and Policies;

POL001 University of Liverpool Sponsorship Policy

SOP004 Sponsorship Application and Approval Process

SOP025 Sponsor Audit

TEM033 LCTC Sole Sponsorship Internal Delegation Plan

TEM022 Non-CTU Sole Sponsorship Internal Delegation Plan

TEM034 External CTU Communication plan

TEM025 Co-Sponsorship Division of Responsibilities template

10. Training and Resources

CIs, students, trial coordinators and other members of University Staff involved in contracting for clinical research activities should be aware of and familiar with this SOP. Training can be provided by the Clinical Research Governance Team upon request (sponsor@liverpool.ac.uk).

11. Monitoring and Audit

An internal audit of Clinical Directorate SOPs will be conducted at a minimum of every two years.