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| **SOP004 Production & Management of Contracts for LJMU Sponsored Clinical Research** |
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| **Relevant to:** | All staff and students conducting research |
| **Approved by:**  |  |
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| **RELEVANT DOCUMENTS** |
|  |
| **RELATED POLICIES & DOCUMENTS** |
| *Governance handbook for LJMU sponsored clinical research**LJMU Sponsorship of clinical research SOPs (numbers 1-10)* |

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# 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 LJMU is to act as the Sponsor of clinical research.

It is of great importance for LJMU to 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 (v3.2 10th October 2017), and it seeks to achieve such compliance through the following procedures.

# 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.

# Procedure

## Who

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

* + - LJMU Research Ethics and Governance (REG);

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

## 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** |
| 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 |
| **Agreement Type** | **Purpose** | **Template Controlled by** |
| 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 Legal and contracts?? Co-Sponsorship Division of Responsibilities template (TEM025) from LJMU REG |
| 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. | LJMU Legal and compliance? |
| Research Site Agreement | Agreements with sites participating in the study (may include material transfer clauses where appropriate). | LJMU Legal and compliance? |
| Material Transfer Agreement | To cover the transfer of material, human or otherwise, between the parties. | LJMU Legal and compliance? |
| Data Transfer Agreement | To cover the transfer of data between the parties. | LJMU Legal and compliance? |
| Confidentiality Agreement | To impose obligation of confidentiality on parties. Often used in the planning stage or when third parties who are not covered by any other agreement involves in a project. | LJMU Legal and compliance? |

Third Party Agreements include contracts, clinical trial agreements, service level agreements, roles and responsibilities documents, forms of work or similar documents. It is expected that LJMU will use nationally approved standard templates where applicable and appropriate.

## How

The number and type of contracts required will depend on the particulars of the Clinical Research Activity. The following sections will detail the most common study types and the procedure for identifying potential contracts:

### NHS Site Agreements

For clinical research that include clinical trials, medical device studies, research using patient data only and research using human tissue - where it has been confirmed that there is no transfer of funds from LJMU as Sponsor to an NHS Site, the CI should generate either a Statement of Activities or a standard Non-Commercial Model Agreement (mNCA) (mandatory for CTIMP studies), which the sponsor will send to the NHS site. For NHS Participating Sites participating in non-commercial, non-interventional research in England or Wales it is expected that a HRA and HCRW Statement of Activities will be used in place of the mNCA.

Where the Statement of Activities is used, this is finalised and dated when the host NHS site confirms capacity and capability. Where a mNCA is used the Research Governance Manager or their delegate is authorised to sign these agreements on behalf of LJMU. Three (3) contracts will be submitted to the NHS site for signature. Once fully signed, a copy must be placed in the Investigator Site File at the NHS site (if applicable), one (1) original to be kept by the NHS site R&D Office, one (1) original to be placed in the Study Master File and one (1) copy sent to sponsor@ljmu.ac.uk.

Where there are funds to be transferred from LJMU as Sponsor to an NHS Site, CI should generate either a Statement of Activities or a standard mNCA and populate the details including the Finance section. Where the Statement of Activities is used, this is finalised and dated when the host NHS site confirms capacity and capability. The Research Governance Manager or their delegate is authorised to sign these agreements on behalf of LJMU. Once fully signed, a copy must be placed in the Investigator Site File at the NHS site (if applicable), one (1) original to be kept by the NHS site R&D Office, one (1) original to be placed in the Study Master File and a copy sent to sponsor@ljmu.ac.uk.

### Clinical Trials

For studies not being managed a CTU the Head of Research Contracts will advise, where appropriate, on any contracts that may be required.

Where contracts are identified as being required LJMU REG will provide the Head of Research Contracts with a copy of the Sponsorship Application form, IRAS form and supporting documents for initiation of agreements.

### Amendments to Contracts

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

# Process for the use of sub-Contracts in support of Clinical Research

It is recognised that Clinical Research sponsored by LJMU may require the engagement of external parties to fulfil services necessary for the fulfilment of the study. This may include:

* External laboratory analyses
* IMP Manufacturers
* Monitoring organisations
* External Clinical Trials Units (CTUs)
* Statistical Support
* Private healthcare facilities
* Clinical Research Facilities

This will require a subcontract with the external service provider. Sub contracts are used to document and agree aspects of the relationship between LJMU and the Third Party organisation(s), including, but not limited to:

* Roles and Responsibilities.
* Financial and legal considerations including indemnity.
* Termination considerations.
* Standards of service.
* Regulatory obligations including Data Protection.
* Intellectual property & publication considerations.
* Confidentiality considerations.

Two (2) originals must be signed by all parties. One (1) original to be kept in the Study Master File, one (1) original for the Third Party organisation, with a copy sent to LJMU REG (sposnor@ljmu.ac.uk).

## Identification of subcontractors

If it is identified by the CI that additional external services are required in support of clinical research, the CI should identify potential service providers. The CI or designated member of the study team should contact the identified service provider(s) to discuss the specific requirements of the study. The CI or designated team member should obtain from the service provider a written proposal for completion of the required work, including where relevant, specific details of the service to be provided; the price to be charged; timings for the provision of the work; details of any external accreditations, external scrutiny etc.

## Assessment of subcontractors

Once the CI has obtained a written proposal for the work from the potential service provider(s) including details of any necessary accreditations, an assessment should be made as to the ability of the provider to deliver the service required, for example, demonstrable compliance with Good Laboratory Practice (GLP) standards or accreditation with an appropriate national process. This should be dependent upon the nature of the service to be provided and could include GLP accreditation or accreditation in an appropriate national process.

## Review and approval of subcontracts

Once an appropriate subcontractor has been identified by the CI, the CI or designated team member should contact WHO? to notify and check costings. Once checked, the CI should provide this information to the Legal and Compliance to initiate contractual negotiations with the service provider.

**The CI is not authorised to sign contracts on behalf of the University.**

## Management of subcontractor’s compliance with contractual requirements

The CI is responsible for monitoring the on-going delivery of the specified work against the stipulations of the contract. Dependent upon the nature of the work to be undertaken by the subcontractor the CI should develop a methodology for assessing contractual compliance.

## Subcontract variations or non-compliance

If the nature of the work to be delivered by the subcontractor changes to that specified in the subcontract or any changes are needed to any other conditions of the subcontract, the Department of Legal Risk and Compliance should be contacted to implement a contract variation.

## Non-compliance with conditions of subcontract

If on assessment of contractual compliance or through the on-going relationship with the subcontractor, the CI identifies issues with non-compliance against the terms of the subcontract the Department of Legal and Compliance should be contacted as soon as possible to discuss the issue and provide advice. The sponsor should be informed about any issues that impact upon the delivery of the study immediately.

# Roles and Responsibilities

The CI, with support from legal and compliance, 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
* Inform the Sponsor(s) of proposed sites and collaborators for the study;
* Ensuring all required agreements are executed before commencement of the research and obtaining advice on these matters;
* Where the study is not being managed by a CTU the CI will ensure that study specific template agreements are held in the TMF or Study Master File.

## LJMU Research Ethics and Governance

* Completion of the Delegation of Responsibilities for Co-Sponsorship Agreements;
* Review the Division of Responsibilities for Research Site Agreements;
* Advise on and oversee the sponsorship application and approval process;
* Register and communicate sponsorship decisions to the Chief Investigator;

## LC – Contracts Team

* Maintain template co-sponsorship agreements;
* Maintain template Research Site Agreements;
* Review and approve funding agreements, supplies agreements; co-sponsorship agreements, amended template Research Site Agreements and amended template material transfer agreements;
* Review and approve post signature amendments to above agreements;
* Provide advice on legal and contractual issues where requested;

## Institute Managers

* Review and approve standard material transfer agreements

# Abbreviations

**CI** Chief Investigator

**CIMD** Clinical Investigation of Medicinal Device

**CTIMP** Clinical Trial of Investigational Medicinal Product

**CTRC** Clinical Trials Research Centre

**CTU** Clinical Trials Unit

**IDP** Internal Delegation Plan

**IMP** Investigational Medicinal Product

**LCTU** Liverpool Cancer Trials Unit

**LC** Legal and Compliance

**PI** Principle Investigator

**RSA** Research Site Agreement

**SOP** Standard Operating Procedure

# Associated Documents and References

# Monitoring and Audit

LC will hold, maintain and release template agreements.

When a research site agreement is received from research sites the TC will cross check the content with the agreed trial template using the compare function in Microsoft Word to ensure all changes are identified.

Once a trial specific template (e.g. RSA) has been agreed by all parties the template will be held in the TMF. Compliance with this SOP will be audited periodically as part of the LJMU REG audit plan.

# Change History

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| --- | --- | --- | --- |
| Version No. | Effective date | Significant changes  | Previous version No. |
| 1.0 | See page 1 | This is the first version of this SOP | n/a |

# Appendices

### Appendix 1 – Authorised Signatories

**Appendix 1 – Authorised Signatories**

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| --- | --- | --- |
| **Department** | **Authorised Signatories** | **Comments** |
| **Legal Risk and Compliance** | Head of Research Contracts and Research Contracts Officers | All agreements |
| **All Institutes** | Institute Managers | For Material Transfer Agreements only |