LinCTU
Lincoln Clinical Trials Unit

UNIVERSITY OF LINCOLN

STANDARD OPERATING PROCEDURE

Site Contracts and Agreement
LinCTU SOP 13

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Next review: 02 years

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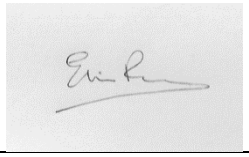
Version History	**Reason for change**
1.0	First LinCTU version

NOTE: All SOPs are subject to regular review.

Please ensure that the version of this SOP is the most up-to-date.

OUT OF DATE DOCUMENTS MUST NOT BE USED AND HARD COPIES SHOULD BE DESTROYED

The following have read, reviewed and advised on the SOP

Reviewer name	**Role**	**Date**	**Signature**
LinCTU Steering Committee	Reviewer	24/10/2022	
Dr Elise Rowan	LinCTU Data Manager	18/07/2022	
Prof Graham Law	Co-director of LinCTU	15/07/2022	

1 PURPOSE

This Standard Operating Procedure (SOP) describes the general procedures for Contracting process for clinical and health-related studies and clinical trials involving the Lincoln Clinical Trials Unit (LinCTU) and sponsored by University of Lincoln (UoL), UK.

2 SCOPE

This SOP applies to all UoL sponsored clinical trials for LinCTU (Lincoln Clinical Trials Unit)

3 BACKGROUND

3.1 The procedures outlined here are aimed to ensure all staff are aware of, act on and adhere to all policies and procedures, guidelines, and relevant legislation applicable to the contracting process.

3.2 Chief Investigator (CI): The CI for each clinical trial will act on behalf of the sponsor to manage the contracting process but may delegate some contract requesting and reviewing tasks to LinCTU trial managers.

3.3 All computers used for drafting, reviewing, negotiating and executing UoL contracts and agreements shall have appropriate security software installed and will be used in accordance with UoL ICT Acceptable Use Policy.

3.4 As sponsor, UoL will ensure that LinCTU investigators maintain control of, and have continuous access to site agreements, contracts and associated amendments throughout the trial. As sponsor, UoL will request updates for regulatory purposes as required.

4 CROSS REFERENCES

CG-QMS SOP CG02 Sponsorship v1.0 01 May 2021

CG-QMS SOP CG05 Ethics Applications Final v1.0 May 2021

CG-QMS SOP CG12 Amendment Final v1.0 May 2021

Contracts (sharepoint.com)

Types of Contact (sharepoint.com)

5 PROCEDURE

LinCTU actively collaborate with the Research and Enterprise Department on behalf of the University of Lincoln to draft, review, negotiate and execute a variety of different contracts and site agreements to facilitate research and other third-party interactions whilst assessing, managing and mitigating inherent risks.

5.1 RESPONSIBILITY AND ROLES

CIs and LinCTU (Lincoln Clinical Trials Unit) will liaise with UoL Research and Enterprise Department for the contracting process for each LinCTU trial/study. The Research and Enterprise Department will ensure all contractual matters are dealt with and addressed and facilitate all aspects of contracting for studies sponsored by University of Lincoln (UoL), UK.

The Chief Investigator (CI) of each LinCTU trial and study will facilitate the interactions with external collaborators and understand how this supports and compliments the contract process.

5.2 INITIATION OF CONTRACTS

The Research and Enterprise Department will review and acknowledge requests for contracts and agreements and may also counsel for meetings to discuss study stimulating funds, dates or any additional contracts that require UoL to enter into. Chief Investigators (CIs) are expected to fully facilitate contracts by providing the knowledge, insights and background for the study/trial. The Research and Enterprise

Department should be contacted in the first instance about any requirements for contracts and agreements by emailing contracts@lincoln.ac.uk.

5.3 DRAFTING OF CONTRACTS

The Research and Enterprise Department will discuss contracting needs in detail with LinCTU (Lincoln Clinical Trials Unit) so that all relevant project aspects are considered in relation to the trial. The Research and Enterprise Department will ensure that contracts and agreements contain all relevant terms and conditions that they are within the law and take into account any relevant regulatory practices, policies and procedures (for example but not limited to, UK data protection, good clinical practice/ clinical trial regulations and relevant university of Lincoln policies).

The Research and Enterprise Department drafts the contracts and will also resolve queries about any proposed or in-process contract changes within the context of the parties, the trial/study and UoL.

5.4 NEGOTIATION OF CONTRACTS

Negotiation of contracts with outside parties will be managed and controlled by the Research and Enterprise Department Team with collaboration and input from LinCTU (Lincoln Clinical Trials Unit) and Chief Investigator (CI) regarding funding, insurance, liability, indemnity, rights and obligations.

5.5 FINALISATION OF CONTRACTS

After agreement to all the terms and conditions by all the parties, UoL as the Lead, the Research and Enterprise Department Team and LinCTU (Lincoln Clinical Trials Unit), the contract will be finalised and will be forwarded for signature.

5.6 SIGNATURE OF CONTRACTS

The final version of the contract/agreement will be signed by all the parties involved in the finalisation of it. The external party involved in the study/trial usually signs first and reviews and acknowledges all the terms and conditions mentioned in the contracts.

Each party will require a copy of the fully signed contract/agreement to keep for their records. LinCTU (Lincoln Clinical Trials Unit) will store finalized signed contracts in the eTMF (electronic Trial Master File) to ensure good documentation practice. Contracts are legal binding documents and enforceable by the courts should one party breach any of their obligations or fail to perform a part of or the contract.

The Research and Enterprise Department will always give final confirmation to all the aspects of the contract and will ensure all the expectations, final illustrations, legislation, law, policies, term and conditions, procedures, responsibilities etc., are clear and unambiguous for all the parties involved in the study.

5.7 MANAGEMENT OF CONTRACTS

The Research and Enterprise Department are responsible for monitoring and managing the contracts. This includes monitoring of the end dates, policies, terms and conditions and whether contract variation and extension is required or not.

TYPES OF CONTRACTS:

This is a non-exhaustive list of some of the potential contracts that Research and Enterprise Department can provide assistance with:

- Agreement Amendment or Variation
- Bespoke Agreement
- Confidentiality Agreement or Non-Disclosure Agreement
- Collaboration Agreement
- Consultancy Agreement
- Framework Agreement or Umbrella Agreement

- Funding or Grant Agreement
- IP Assignment Agreement
- Licence Agreement
- Material Transfer Agreement
- Research Sub-contract
- Memorandum of Understanding (MOU)
- Novation Agreement
- Studentship Agreement
- Clinical Trial Agreement (CTAg)
- Clinical Trial Agreement Amendment
- Letter of Indemnification (LOI)

Further details are provided in the links found in section 4 above.

6 FLOW CHART

None required