University of Hertfordshire

CONTRACTS AND AGREEMENTS FOR UH SPONSORED AND CTSN SUPPORTED CLINICAL STUDIES

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for Contracts and Agreements for University sponsored and CTSN supported clinical studies at the University of Hertfordshire (UH)

SOP Number: gSOP-03-01	**Effective Date:** 16th March 2022
Version Number: 1.0	**Review Date:** 2 - 3 years (or as required)

1.0 BACKGROUND

Where policy or legislation necessitates that a clinical research study has a Sponsor, it is a requirement of the Sponsor to document clear agreements describing the allocation of roles and responsibilities.

2.0 PURPOSE

To provide the processes and guidance required for preparing, negotiating and amending contracts and agreements for clinical research studies where UH is the sponsor.

Agreements may include, but are not limited to:

- Co-sponsorship agreements.
- Collaboration agreements.
- Clinical Trial Agreements with sites and other providers.

To describe the process for the implementation of trial agreements with sites.
To ensure that the financial arrangements are transparent and that they follow the terms and conditions of the funding agreement.

3.0 APPLICABLE TO

This applies to all staff involved in clinical research sponsored/co-sponsored by UH, including but not limited to: Chief Investigators (CI), Principal Investigators (PI), Research Fellows, Consultants, Statisticians, Clinical Trial Pharmacists, Research Managers, Research Nurses, Clinical Trial Practitioners, Allied Health Professionals, Trial Co-ordinators/Managers, Clinical Studies Officers, Data Managers Research Assistants and Students.

4.0 RESPONSIBILITIES

The CI or delegate has the responsibility to provide the appropriate information required to UH legal for the preparation and execution of the necessary contracts. They will also inform UH legal of any changes or updates to the conduct of the study that may necessitate post signature changes to the contractual requirements.

UH Legal has the responsibility to generate the agreement (or comment upon and amend agreements provided by other parties) and manage the contract process to full execution.

The clinical trial manager has the responsibility to distribute the fully executed contract to all parties.

All members of the University engaged in research are required to declare any circumstances where the commitments and obligations owed by them to the University or other bodies, for example funding bodies, are likely to be compromised by that person's personal gain (UPR GV12).

5.0 PROCEDURES

Before commencing a clinical trial, an agreement will need to be produced, agreed and signed by all relevant parties. The sponsor is usually responsible for the preparation of the agreement however this can be assessed and agreed between the parties.

Any conflicts of interest, financial or non-financial in relation to the research will be noted and addressed by UH Legal within the contract.

5.1 Discuss the project with the Data Protection Officer (DPO)

At the start of the project a meeting should be held with the DPO at UH (dataprotection@herts.ac.uk). Answers to the following questions should be prepared and discussed:

- What data will be generated and processed and by whom?
- Who will be the data controller?
- Where will the data be held/secured?

- Who will the data be shared with?
- How will the data be transferred?
- Will the data be anonymised/pseudonymised?
- What privacy notices will be required to be provided to the data subjects?

A Data Protection Impact Assessment will be prepared in consultation with the DPO and will be kept up to date during the project.

5.2 Arrange an initial meeting with the UH Legal Team

The UH legal team (either the Senior Solicitors or at their discretion the Contracts Officers) should be contacted and an initial meeting or call arranged to discuss the project and the appropriate form of the agreement.

The legal team will draft an agreement which is proportionate to the level of risk associated with the study and the type/nature of the organisation(s) involved. The UH legal team has a suite of templates that can be used for projects. The UH legal team will ask a number of detailed questions in order to establish how the project will operate and what legal matters need to be taken into consideration and discussed with all relevant parties.

The following aspects will be included within the agreement:

- Roles and responsibilities;
- Financial and legal considerations including indemnity;
- Termination considerations;
- Standards of service;
- Regulatory obligations including Data Protection;
- Intellectual property and publication considerations;
- Confidentiality considerations.

Prior to the meeting or call with the UH legal team information regarding who the agreement will be between, the roles of the parties and the funding agreement (including any requirements of the funder in relation to the intellectual property generated as part of the project) should be sought.

During the initial meeting or call, the deadline for full execution of the agreement should be communicated.

5.3 Registration on the UH Contract System

Following direction from the initial meeting or call, a case should be opened on the UH contract system (ipacs@herts.ac.uk). **Ensure the deadline for completion is made clear.**

5.4 Generation, review and finalisation of contract

The UH legal team will generate and manage the contract process to full execution.

The contract will be circulated to all parties for review and comment (this may go through several cycles depending on comments).

Prior to being sent out for signature, the final version **must** be approved by the Dean of the school concerned.

For NIHR funded projects the approved contract should be sent to the NIHR Project Manager for approval prior to execution.

The approved contract will then be sent to all parties for signature (this may be via Core Signature).

Once all parties have signed the contract, it is fully executed (FE). The FE contract should be circulated to all parties.

5.5 Storing on EDRMS

A partially completed Contract Storage Checklist will be sent by the legal team with the FE contract. The trial manager or designated individual should complete the Contract storage checklist. The completed checklist should be sent with the FE contract to the appropriate departmental administrator who will upload the FE contract onto the EDRMS.

See Appendix 1 for Flow chart of process.

6.0 RELATED DOCUMENTS

- UPR GV12

7.0 APPENDICES

Appendix 1 – Process Flow for contracting process for clinical trials at UH

8.0 VERSION HISTORY/REVISIONS

Version Number	Effective Date	Reason for Change

9. AUTHORSHIP & APPROVAL

Author Solange Wyatt

Signature  **Date 15/03/2022**

Pro-Vice Chancellor (Research and Enterprise) Approval

Signature  **Date 01/03/20**

Appendix 1 – Process Flow for contracting process for clinical trials at UH

1. Arrange a Meeting

- Contact a senior solicitor within the University of Hertfordshire legal team to arrange a meeting either with them or a member of the contracts team to discuss your research contract needs.
- Gather as much information about the project and specific requirements/considerations prior to the meeting.
- Before the meeting discuss the project with the UH Data Protection Officer ("DPO") and prepare answers to the following questions:
    - What data will be generated and processed and by whom?
    - Who will be the data controller?
    - Where will the data be held/secured?
    - Who will the data be shared with?
    - How will the data be transferred?
    - Will the data be anonymised/pseudonymised?
    - What privacy notices will be required to be provided to the data subjects?
- Note a Data Protection Impact Assessment will need to be prepared in consultation with the UH DPO and should be kept up to date during the project.
- In addition, before the meeting, prepare answers (to the best of your knowledge) to the following questions:
    - What Intellectual Property will be generated during the project ("Arising IP")?
    - What do the funding terms state in relation to ownership of Arising IP?
    - What rights will each of the parties working on the project and the funder want to access and use the Arising IP?
    - Who will the contract be with?
- At the meeting ensure that a deadline for completion is discussed and agreed.

2. REGISTRATION

Following direction in your initial meeting, open a case on the UH contract system.
Ensure the deadline for completion is made clear.
Register with IPACS to use the IPACS service
N.B:

- You must be logged into the staff network via pulse secure to access.
- Use your university email address to log in.

3. REQUEST A SERVICE

- Log in to IPACS using your username and password. Click on 'request service' (bottom of the My Cases box on the right).
- If you know which service you want, click ***request a specific service*** then ***start a new case*** then ***draft a research agreement***. You will get faster and more effective support this way.
- If you don't know which service you need, click ***all other requests***
- Visit https://herts365.sharepoint.com/sites/Legal-and-compliance/SitePages/Contracts.aspx for more guidance.

4. CONTACT FROM LEGAL

- The legal team will pick up your request and get in contact.
- They will discuss which type of research agreement that has been selected e.g. contract with funder, collaboration agreement, site agreement, and what further information is required to progress the contract. Provide as much information as you can to the legal team so that they can include within the agreement the appropriate terms.
- Research does not usually attract VAT, but this should be checked with finance beforehand and appropriate wording to be added into the contract if exempt.
- A schedule for the production of the contract should be agreed: date first draft available, date final draft agreed, date Fully Executed contract completed etc. noting that the contract will be delayed if parties do not respond in a timely way or there is any disagreement as to the terms of the agreement. Provide assistance to the legal team by diarising and chasing up parties who have not responded with comments on the draft agreement.

5. REVIEW AND FINALISING OF CONTRACT

- The legal team will generate and manage the contract process to full execution.
- The contract will be circulated to all parties for review and comment (this may go through several cycles depending on comments).
- Prior to being sent out for signature, the final version **must** be approved by the Dean of your school.
- For NIHR funded projects send approved contract to the NIHR Project Manager for approval prior to execution.
- The approved contract will be sent to all parties for signature – this may be set up by legal via DocuSign.
- Where necessary send approved and signed contract to legal for final sign off and execution by UH.

6. FINALISED CONTRACT

- Once all parties have signed the contract, it is fully executed (FE). Circulate FE contract to all parties.
- A partially completed Contract Storage Checklist will be sent by the contract team along with the FE contract.

7. STORING ON THE EDRMS

- Project Manager or designated individual should complete the Contract Storage Checklist.
- Send the completed checklist along with a signed copy of the contract to your dept administrator who will upload the contract onto the EDRMS.

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 gSOPXXX) and accept to follow University of Hertfordshire policies implementing it.

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

Please retain copy of the signed form for your reference in your training file