STU-SOP-TS-013 – Standard Operating Procedure on Contract Requirements for Non-commercial Research Projects

1. Purpose and Definitions

This Standard Operating Procedure (SOP) describes the procedure of issuing and completing the required contracts for non-commercial Clinical Trials of Investigational Medicinal Products (CTIMPs), Device Trials and where required, other research projects.

Definitions	
Contract	A written agreement used between the trial Sponsor(s) and any internal or external party. The contract defines the terms and conditions associated with the specific trial-related tasks delegated to a party.

2. Background

The Sponsor role for CTIMPs and Device Trials is defined under UK legislation. Sponsor(s) may formally delegate tasks related to contracts, but ultimately remain legally responsible for conduct of the CTIMP/Device Trial. The sponsor is required to implement sufficient processes to maintain oversight to ensure that legislation is complied with, and the sponsor's legal responsibilities are met.

Additionally, funders will require specific contracts to be in place for individual research projects aligned to the details of the award with the host institution.

3. Roles and Responsibilities

The **Sponsor(s)** has ultimate responsibility for the management and/or financing of the research project. Although tasks may be delegated the Sponsor must ensure that appropriate contracts are in place for any research project.

Swansea Trials Unit (STU), when delegated, are responsible for ensuring that sponsors legal responsibilities are met by the generation and execution of contracts identified as a requirement for individual research projects.

The **Chief Investigator** (CI) must ensure that activities covered by contracts are not implemented until the relevant contracts and all required approvals are in place. The CI must also ensure that all contracted parties or collaborators receive a copy of the approved trial protocol, any amendments or other associated documentation.

NHS organisations and Academic Organisations, when sponsors, and through their delegated **departments** are responsible for drafting and ensuring that appropriate contracts are in place to arrange for the legal, financial, and administrative management of the trial.

The **Trial Manager** (TM) when delegated responsibility from the CI will liaise with relevant parties in NHS, academic and external parties as required to facilitate drafting. review and signatures of all contracts.

External use of SOP: this SOP and Associated Documents (AD) may be used for research projects not adopted by STU where Swansea University (SU) staff and associated NHS

organisations require guidance. In such instances, oversight responsibility for any associated tasks will not be the responsibility of STU.

4. Procedure

4.1 Contracts for Non-commercial CTIMP and Device Trials

Contracts must be in place for regulated CTIMPs and Device Trials.

The sponsor will identify what legal contracts are required from the scope of the research project and the funder award. They will be aided by the CI, TM, and STU Manager, as appropriate.

The CI and TM (when delegated) are responsible for liaising with the sponsor to coordinate a finalised contract and dissemination where required.

Where delegated responsibility STU will manage a vendor/third party assessment.

4.2 Contracts for all other research

Contracts are not always required for non-regulated research projects.

The sponsor will make a decision on individual projects aided by the CI, TM and STU Manager as appropriate.

The CI and TM (when delegated) are responsible for confirming what contracts, if any, are required with the sponsor and for coordinating a finalised contract and disseminating where required.

4.3 Identification of contracts required

Following receipt of a favourable response from the host institute, the funder may issue a research contract/funder agreement to the employing organisation of the CI.

The CI, STU, TM and other designated parties as required will review and agree to the terms and conditions of the contract, and the responsibilities of the Sponsor and CI. It will be signed off by relevant parties in academic and NHS organisations

The TM shall ensure that a copy of this contract is retained in the Trial Master File (TMF), and that the terms and conditions are followed.

Commercial template contracts/agreements will be used e.g. National Institute of Health Research Templates (NIHR). Where relevant a sponsor or third-party template may be used.

4.4 Preparing, negotiating and storing trial contracts

The generic procedure for preparing, negotiating and storing contracts is detailed below.

Where STU is sub-contracted as a service provider, e.g. database provision, trial management. The CI, STU and sponsor will agree a schedule of responsibilities to be included in a sponsor agreement.

The CI, STU and sponsor will draft contracts based on existing templates where possible.

All academic and NHS organisations will seek approval of the draft agreement from departments e.g. Clinical Trials Pharmacy as necessary. Where required, organisations will conduct a consistency review to ensure contracts do not conflict.

The Sponsor or CI will issue the draft contracts to the external party for review. Negotiation of the trial agreement will be led by the sponsor.

The Sponsor will seek advice and approval of any changes to the contract from STU, CI, TM, and other parties involved e.g. Trial Pharmacist as required.

The Sponsor organisation will manage the final approval and signature process supported by the TM when necessary.

Hard copies, or electronic contracts may be issued for signature. In general, the Sponsor will be the last party to sign. Dissemination of signed copies will be managed by the CI/TM, and other parties as required.

The TMF will indicate details of where the original signed copy will be held.

Sponsor, CI, and TM will liaise, if required, to draft amendments to the contracts following these procedures.

It is the CI's responsibility to ensure contractual amendments are not implemented until any associated regulatory, ethical and R&D amendments are approved as required.

Where necessary the Sponsor or STU (when delegated) will contact the Sponsor's provider of clinical trials insurance to notify them of the amendment to ensure that cover will be in place.

5. References

- Health Research Authority website (HRA) - http://www.hra.nhs.uk/
- Medicine and Healthcare products Regulatory Agency website (MHRA) - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information
- UK policy framework for health and social care research (2017) - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- UK Medicine for Human Use (Clinical Trials) Regulations 2004 - http://www.legislation.gov.uk/uksi/2004/1031/contents/made
- NIHR : Model site agreements (model contracts, standard research agreements) | NIHR

It is assumed that by referencing the principal regulations that all subsequent amendments are included in this citation.

6. Associated Documents

Number	Title	Location
N/A	N/A	N/A

7. Abbreviations

List of Abbreviations	
CI	Chief Investigator
CTIMP	Clinical Trials of Investigational Medicinal Products
MHRA	Medicines and Healthcare products Regulatory Agency
R&D	Research and Development
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University
TM	Trial Manager
TMF	Trial Master File

8. Appendices

Appendix 1: Document History

Version No:	2	**Effective Date:**	22-Apr-2024
Description of changes:	Updated to SOP Template v5		

Appendix 2: Contract types

Trial Agreement Type	To be in place prior to:	Key Points*:
Funding Agreement	Any other contracts being signed	The grant holder/sponsor will check and approve the contract with the trial funder
(Co)Sponsorship Agreement	Trial recruitment at any site can commence (*N.B. recruitment cannot commence until all required approvals are in place)*	The Sponsor will draft either a Co-sponsor agreement or a Co-sponsor site agreement as required.
Site Agreement	Site recruitment at that site *(N.B, recruitment cannot commence until all required approvals are in place)*	The STU Manager or delegate and sponsor will agree Schedule 2, Delegations of Responsibilities.
Pharmacy Agreement	Medicinal product being sent to site	May be part of a site agreement or separate if independent pharmacies are involved.
Collaboration Agreement	Any work beginning on the project. Collaborator receiving any trial data or samples	Required where the investigators involved in the design of research and delivery are over multiple organisations. Where data or samples are to be transferred there may be a requirement for multiple contracts.
Co-enrolment Agreement	Recruiting participants into more than one trial	Sponsor shall determine if a formal agreement is required prior to co-enrolment.
Medicinal Product/Device Supply Agreement	Sign off of Trial Authorisation Form (*Green Light)*	A vendor assessment may be required. The Sponsor will draft the Medicinal Product/Device Supply Agreement and/or Technical Agreement, or will review the draft agreement if this is sent by the supplier

		Where a third party's template contract is used, review and negotiation of the third party's terms of service may also be required in conjunction with the supply agreement and will be led by the Sponsor or STU Manager.
Questionnaire Licenses	Prior to site initiation and recruitment. N.B.	Sometimes required to use a validated instrument. Usually negotiated through the CI/TM and licensing organisation.
Laboratory / Service Agreement	Receipt of samples by any external laboratories or other third parties sub-contracted for the trial	A vendor assessment may be required. The STU Manager or delegate shall review and approve a services schedule, which where necessary, will form a schedule to the contract. Where a third party provides their own contract template the STU Manager or delegate will assess whether a separate services schedule is also required.
Material Transfer Agreement	Any trial materials being transferred to a third party	The Sponsor will assess whether a separate MTA is required. There may be instances where a clause addressing handling of trial samples should be included within one of the other trial agreements. e.g. collaboration agreement.
Confidentiality/Non Disclosure Agreement	An organisation disclosing any of their intellectual property.	Signed by individuals and legally binding.

Data Sharing /Data Access Agreement	Receiving, accessing, or sending data through a third party.	

* The Sponsor is responsible for generating all contracts. The CI, STU Manager, TM and others as required will help identify and assess content of the contracts as required. Contracts are usually signed by the Sponsor or employing organisation. Rarely by an individual.