

SOP Number 016
SOP Title Contracts for Clinical Research Studies

	Name	Title	Signature	Date
Author on behalf of the QA Focus Group	Kate O'Neill	QA Specialist, Clinical Trials and Research Governance		MAY 6, 2020
Reviewer on behalf of the QA Focus Group	Elaine Chick	Deputy Head of Clinical Trials and Research Governance		20th May 2020
Authoriser	Heather House	Head of Clinical Research Support (University Lead of the Joint Research Office)		20th May 2020

Agreed by QA Focus Group	30 th April 2020
Effective Date	20 th June 2020
Review Date	19 May 2023

1. PURPOSE

This SOP describes the procedures used by the University of Oxford for the provision and management of agreements with external organisations for clinical research studies, where the University is the Sponsor under the relevant regulatory requirements.

2. INTRODUCTION

Clinical research studies often involve agreements with external organisations, such as funders, research sites, collaborators, laboratories and drug/device suppliers. Where policy or legislation necessitates that a clinical research study has a Sponsor, it is a requirement of the Sponsor to document clear agreements with relevant external organisations; describing tasks, duties, functions between parties and, where relevant, any required standards of service.

According to the University's Financial Regulations, Research Services is responsible for negotiating research and research-related contracts and grant conditions on behalf of the University. This SOP describes the procedures that are followed by the University of Oxford to ensure these responsibilities are met. As the agreements required can vary considerably depending on the nature of the study, this SOP aims to reflect considerations which are generally applicable.

3. SCOPE

The scope of this procedure is for all Agreements with external organisations negotiated by the University of Oxford Research Services relating to all clinical research studies.

Subject to the funder's terms and conditions for the procurement process, all contracts for the purchase of goods and/or services under £100,000 which are not on standard University terms, and those over £100,000, must be negotiated through the University Purchasing Department. Agreements handled by the Purchasing Team therefore fall outside the scope of this SOP. This SOP also does not cover construction related contracts handled by Estates Services nor employment contracts handled by University Human Resources teams.

Agreements that are handled within University Research Departments also fall outside the scope of this SOP. Departments should be contacted regarding specific procedures to be followed.

4. DEFINITIONS

Sponsor

The person/organisation who takes responsibility for the initiation, management and financing (or arranging financing) of the study. The University of Oxford as Sponsor is represented by the Clinical Trials and Research Governance Team (CTRG).

Chief Investigator

An individual who is responsible for the conduct of the whole of the project.

Contract/Agreement

For the purpose of this SOP, references to a Contract or an Agreement refer to Agreements with external organisation(s) negotiated by the University of Oxford's Medical Sciences Research Services Contracts Team relating to clinical research studies sponsored by the University of Oxford, excluding those handled by the Purchasing Team, Estate Services or the University Departments in accordance with the Financial Regulations.

Organisation Information Document (OID)

A key component of the UK Local Information Pack for research projects, used to provide information to participating NHS/HSC organisations. Depending on the nature of the study, this document may be used to form the Agreement(s) between the Sponsor and the participating NHS/HSC organisation(s).

C(B) Form

A form for persons engaged in research who are not employees of the University and are not parties to an Agreement governing the research, to document their agreement to abide by the terms and conditions of Agreements and/or grants relating to the research that they are involved with. In the main this applies to University of Oxford students, but in exceptional circumstances this form can be used for persons from other organisations when this is not covered elsewhere.

External Organisation

These could be considered to be, but not limited to:

- Funders
- Collaborators
- Participating sites (clinical and non-clinical)
- Suppliers of medicinal products, placebo, devices or other equipment
- Providers of information/data/samples

External Organisation Agreement

These could be considered to be, but not limited to:

- Funding agreements
- Collaboration agreements
- Confidential disclosure agreements
- Clinical trial agreements
- Material transfer agreements

Framework Agreement

An overarching master agreement setting out the terms that apply to all arrangements of a particular type between the University of Oxford and an external organisation.

5. RESPONSIBILITIES

Chief Investigator or delegate

- Ensure that the Contracts Team are provided with sufficient information in advance of the study start to assist them in their responsibilities.
- Read Agreements with external organisations, sign in acknowledgment (where required), and file appropriately.
- Ensure that any students sign C(B) forms where requested by the Contracts Team, and file appropriately.
- Ensure that Agreements are fully executed prior to commencing the concerned activity.
- Undertake ongoing and end of study review of Agreement(s) and ensure adherence to the terms and conditions.
- Inform the Contracts Team of any changes or updates to conduct of study that may necessitate changes to the contractual requirements.

Medical Sciences Research Services Contracts Team (Contracts Team)

- Ensure all Agreements with external organisations are reviewed, negotiated, and drafted (where necessary) with responsibilities of all parties documented.
- Request institutional signatures from all parties to the Agreement.
- File and distribute copies of each Agreement with an external organisation(s) as required.
- Ensure proposed variations to the contract which are notified to the Contracts Team are appropriately reviewed and, where a written amendment to the contract is required, that this is drafted/reviewed as appropriate, and negotiated with the relevant external organisations.
- Where required, send C(B) form(s) to CI or delegate.

Clinical Trials and Research Governance Team (CTRG)

- Direct the CI or delegate to contact the Contracts Team for identification of contractual requirements. This should also be done following amendments to the study, if appropriate.
- Review OID(s) that will serve as Agreement(s) with any participating NHS/HSC organisation(s), if appropriate.

Risk and Insurance Manager (Research) (RIM)

- Provide specialist advice, based upon the Sponsor's clinical trials and related liability insurance. Review and assess study design, and consult with insurer/broker if appropriate.

6. SPECIFIC PROCEDURE

6.1 Identification of External Organisation Involvement

The CI or delegate should contact the Contracts Team at an early stage to inform of the possible need for contractual involvement with external organisations in relation to their clinical research study. If necessary, a meeting should be arranged with the Contracts Team to further discuss details of the arrangements. If a study risk assessment meeting is held, the Contracts Team should be invited to gain early insight into potential contractual considerations. For University Sponsored studies, CTRG will also direct the Study Team to the Contracts Team if processes

potentially requiring external organisation Agreements are identified during early Sponsorship discussions.

A protocol should be provided to the Contracts Team (see CORE SOP 002 – Protocol Development). Other key documents that outline contractual considerations should also be provided, at a minimum this should include the Participant Information Sheet, Consent Form, and the Integrated Research Application System (IRAS)/Clinical Trial Application (CTA) form, as applicable. The CI or delegate should also send a copy of these documents once approved by the Sponsor, so that Contracts Team are aware of the final study design.

6.2 Negotiation of External Organisation Agreements

6.2.1 General considerations

The form of the Agreement with the External Organisation will depend on the context of the study and the relevant arrangements. The University will use nationally approved standard templates where applicable and appropriate.

Agreements can be in the form of a study-specific Agreement, or alternatively there may be a Framework Agreement where individual studies can be added by way of amendment to that agreement.

The External Organisation Agreement should document, where applicable, the agreed position as to (but not limited to):

- Roles and responsibilities
- Liability
- Data/Material Transfers (where applicable)
- Confidentiality
- Intellectual property & publication
- Termination

All parties should pay particular attention to University insurance policies and scope, and those expected of the external organisation. If the external organisation is outside of the UK, consideration should be given to any territory-specific requirements. If necessary a draft contract should be sent to the Sponsor RIM to ensure that all indemnity issues are addressed in the Agreement.

6.2.2 Special considerations for Agreements with participating sites

For agreements with participating sites, a nationally approved standard template should be used. Where this is not appropriate, the template will specify the requirement to comply with the approved protocol, relevant regulations and Good Clinical Practice where applicable.

For University sponsored studies, the Contracts Team will confirm with CTRG whether it is appropriate to use the OID as an Agreement between the Sponsor and any participating NHS/HSC site(s). In this case, the CI or delegate will work with CTRG to finalise this Agreement.

6.2.3 Special considerations for students

University of Oxford students do not hold a contract of employment with the University, and so they must agree to any terms and conditions associated with the study by signing a C(B) form. If

required, a C(B) form will be sent by the Contracts Team to the CI or delegate, who must ensure that this is completed and signed by the student prior to their involvement in the study, and filed appropriately.

6.3 Execution of Agreements with External Organisations

Once all parties have agreed to the terms the Contracts Team will seek signature of the agreement by an institutional signatory with authority to sign research-related contracts on behalf of the University.

All concerned parties must sign the Agreement. Where there is an 'Effective Date', this must be completed.

The Contracts Team will store a pdf copy of the fully signed Agreement(s) with external organisations on their internal system, and will send a pdf copy to the relevant academic department for their records. Relevant other parties will also be sent a pdf copy. If the Contracts Team holds paper copies of fully executed contracts containing wet ink signatures from all parties, these will be sent for archiving centrally at the University Offices at Wellington Square.

The CI or delegate must check that all Agreements with external organisations are finalised, signed and dated before filing. Copies with signatures from all parties should be retained. It is not necessary to retain partially signed copies, unless dictated by local policy or if deemed appropriate by risk assessment. Whether to retain paper copies with wet ink signatures when there is a corresponding electronic copy is also a local decision, which could be determined by risk assessment. . If the study is a clinical trial, copies should be filed in the Trial Master File.

The activities covered by an Agreement should usually only commence once the relevant Agreement has been fully executed. Under no circumstances should study-related activities at participating sites commence prior to this.

6.4 Ongoing Review

Agreement(s) should be periodically reviewed by the CI or delegate to ensure that the terms and conditions are being adhered to, in particular if there has been a change to the design or conduct of the study.

6.5 Amendments

The CI or delegate must alert the Contracts Team to any changes to the design or conduct of the study that may have an impact on Agreement(s) with external organisations. Key study documents should be provided to the Contracts Team as outlined in 6.1. Any relevant changes to an External Organisation must also be alerted, such as an organisation being taken over or going into administration.

For University Sponsored studies, CTRG will also direct the CI or delegate to the Contracts Team if they become aware of any amendments to the study that might require contractual consideration.

6.6 Duration

6.6.1 Expiry

The CI or delegate is responsible for ensuring contractual obligations are met when the expiry date is reached, such as equipment returns or handling of confidential information. The Agreement may also outline activities to be undertaken after the expiry period (eg. sample handling, record retention), and the CI or delegate should ensure that these survival clauses are adhered to.

6.6.2 Early termination

Grounds for early termination, and the subsequent procedures to be followed, will be outlined in the Agreement. Where appropriate, the CI or delegate will work together with the Contracts Team to arrange any necessary documentation.

7. RELATED DOCUMENTS

University of Oxford Core SOP 002 – Protocol Development

8. REFERENCES

<https://www.admin.ox.ac.uk/statutes/regulations/101-078.shtml>

<https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack-OID>

9. CHANGE HISTORY

Version No.	Effective Date	Significant Changes	Previous Version No.
1.0		First version of SOP	n/a