Standard Operating Procedure

Title:	**Contracting Procedure for Clinical Trials of Investigational Medicinal Products (CTIMPs)**		
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	Name and Position	**Signature**	**Date**
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1. Purpose

This Standard Operating Procedure (SOP) describes the procedure to be followed when contracting for Clinical Trials of Medicinal Products (CTIMPs) is required and the University contracts out clinical trial services to a third party. This document applies to CTIMPs for which Queen's University of Belfast is involved in the contracting process.

2. Responsibilities

2.1 Sponsor

The Sponsor role for CTIMPs is defined under the UK legislation. Sponsor(s) have specific responsibilities and may formally delegate tasks, but ultimately remain legally responsible for conduct of the CTIMP. Therefore, 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. The University does not Sponsor CTIMPs.

2.2 Chief Investigator

The Chief Investigator (CI) is responsible for highlighting the need for a contract with other parties at the earliest opportunity and must notify the Research Contracts Team, in the Research and Enterprise Directorate to enable them to plan ahead.

Where external partners are to be used, the CI is responsible and must be able to verify that each contractor is competent to undertake the role for which they have been tasked and that they meet all regulatory standards.

The CI must report any adverse events/anomalies defined in the protocol as being critical to safety evaluations within a pre-set time period to the Sponsor and/or the MHRA directly.

2.3 Research Contracts Team

The Research Contracts Team will be required to negotiate and subsequently produce a legally binding contract acceptable to the parties involved, where the University is the lead partner in receipt of funding. It is the responsibility of the CI to ensure all matters relevant to the delivery of the trial are raised with the Research Contracts Team to facilitate due diligence.

2.4 Research Governance, Ethics and Integrity Team

The Research Governance, Ethics and Integrity (RGEI) Team will provide guidance to both CI and Research Contracts upon request.

3. Procedure

3.1 QUB Funding Lead

Where the University is the lead partner in receipt of funding for the CTIMP, the Research Contracts Team, with support from the CI and RGEI Team will draft the contractual arrangements.

Once funding has been awarded, Faculty Finance will inform the Research Contracts Team via the RAS/RGD system or Contracts Request Form (CRF) as appropriate and representatives of Faculty Finance, Research Contracts, RGEI Team, the CI and the Sponsor shall liaise to enable the identification of the parties involved and all required contracts for the trial. These discussions may also involve relevant external parties (eg Belfast Health and Social Care Trust, Northern Ireland Clinical Trials Unit).

Where the University is providing indemnity in relation to a CTIMP, the University's insurer must be informed and a referral made in accordance with their procedures. For trials that are

sponsored by Belfast Health and Social Care Trust, the associated Research Governance Manager for the trial shall be responsible for referral. For trials sponsored by all other organisations this referral shall be undertaken by the Contracts Manager/Officer responsible for the trial. The University's Insurance Office (Insurance@qub.ac.uk) must be copied on all correspondence.

The draft trial agreement(s) shall be issued to the other party/parties for review. The Contracts Manager/Officer assigned the matter shall lead negotiations until the contractual agreements have been agreed. The Contracts Manager/Officer will seek advice and approval of any changes to the trial agreement from the Sponsor, CI and RGEI Team as required.

The Research Contracts Team shall be responsible for issuing the contract to relevant parties for signature by the appropriate authorised signatory.

The Trial Agreement shall be approved following signature by authorised signatories of each contracting party. The Contracts Manager/Officer shall manage the signature process.

Final signed trial agreements will be retained in the Trial Master File. A copy will also be retained in Contracts Matter file on Repstor.

Final authorisation of trial agreements on behalf of the University is the responsibility of the authorised signatories as detailed in the Research and Enterprise Scheme of Delegation.

Any requests for subsequent amendments to final signed trial agreement(s), must be referred to the Contracts Manager/Officer. The Contracts Manager/Officer will seek advice and approval of any proposed changes to the trial agreement from the Sponsor, CI and RGEI Team as required and lead the amendment process.

3.2 QUB Not Funding Lead

Where the University is not the lead party on the funding award for a CTIMP, the Research Contracts Team, with support from the CI and RGEI Team will review and negotiate the contractual arrangements provided by the lead partner on the funding award or Sponsor. The CI is responsible for logging the matter with the Contracts Request Form on Queens Online.

Final authorisation of trial agreements on behalf of the University is the responsibility of the authorised signatories as detailed in the Research and Enterprise Scheme of Delegation.

Final signed trial agreement(s) will be retained in Contracts Matter file on Repstor.

4. Types of Agreements*

Type of Agreement	Purpose
Non-disclosure Agreement	To establish a confidential relationship restricting unauthorised access.
Material Transfer Agreement (MTA)	To govern the transfer of material from the provider to the recipient. This may include biological samples but can also govern other chemicals, reagents – indeed anything with scientific or commercial value. There may be instances where clauses addressing handling of trial samples can be included within one of the

	other trial agreements.
Service Level Agreements	Details of the service and the required standards by a specific provider.
Funding Agreements	Details of the funding to be granted to the University.
Site Agreements	Entered into with the site on which trial activities are to be conducted, for example, with NHS/HSC Trust and detail responsibilities with regards to conduct on the trial. Where this involves NHS/HSC Trusts the relevant national model agreement should be used.
Laboratory Agreements	Agreements with the laboratory that will provide services to the Trial, stating that the work must be undertaken to GCP standards.
Collaboration Agreements	Where another institution is working in association with the University in terms of trial data or clinical samples.
Medicinal Product Supply Agreement	Where an Investigational Medicinal Product is required for the trial from an external supplier
Sponsorship/Co-sponsorship Agreement	An agreement to delegate responsibilities between parties.
Data Sharing/Access/Transfer Agreement	An agreement between parties to exchange a limited data set for the purpose of furthering research. Depending on whether the agreement does or does not include Personal Data (information from which a living individual may be identified or identifiable) the terms and required QUB signatories will vary, so as to ensure appropriate treatment of the exchanged data under the applicable data protection laws.
Amendment	Where the start date, previously agreed with the funder, requires deferral.

**Not all types of agreements will be applicable to a CTIMP*

5. References

Medicines for Human Use (Clinical Trials) Regulations 2004 (the Regulations) http://www.legislation.gov.uk/uksi/2004/1031/contents/made (last accessed 04 May 2022)

Good Clinical Practice (GCP) MHRA Website http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/index.htm (last accessed 04 May 2022)

Good Clinical Practice for Clinical Laboratories MHRA Website https://www.gov.uk/topic/medicines-medical-devices-blood/good-practice (last accessed 2 04 May 2022)

Good Manufacturing Practice MHRA Website https://www.gov.uk/topic/medicines-medical-devices-blood/good-practice (last accessed 04 May 2022)

ICH GCP Guidance http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html (last accessed 04 May 2022)

EU Clinical Trials Regulation (EU) No 536/2014 https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation (last accessed 04 May 2022)