Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Contracting Procedure for Clinical Trials of Investigational Medicinal Products (CTIMPs)**		
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	Name and Position	**Signature**	**Date**
Author:	Dr Stephen Liggett Research Governance Manager	----------	----------
Reviewed by:	Mrs Louise Dunlop, Head of Research Governance	----------	----------
Approved by:	Professor James McElnay, Chair Research Governance Steering Group	----------	----------

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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
v1.0	06/10/2014	Periodic Review	v2.0
Final v 2.0	19/12/2016	Periodic Review	Final v 3.0

1. Purpose

The outsourcing of services associated with Clinical Trials of Medicinal Products (CTIMPs) is usually a necessity. Rarely does an organisation have the resources available to fully conduct the entire study within their organisation. Sponsors depend on external contractors capable of delivering high quality services to efficiently manage CTIMPS. This procedure has been compiled to ensure that the appropriate considerations are taken when the University contracts out clinical trial services to a third party.

2. Introduction

Conducting a CTIMP is a complex process involving expertise in a wide range of areas. Typical services that are provided by clinical trials service companies include, but are not limited to:

- Laboratory services
- Clinical laboratory services
- Clinical facilities
- Clinical procedures
- Regulatory
- IMP manufacture
- Comparator sourcing and blinding
- Labelling and packaging
- QP release
- Supply-chain management
- Project management
- Pharmacovigilance
- Indemnity Insurance
- Site Monitoring
- Emergency provision if required.

The Sponsor of a clinical trial assumes overall accountability for all regulatory requirements defined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (the Regulations)[1].

A Contract Research Organisation (CRO) may be appointed to assume the responsibility for any or all parts of a CTIMP. However, this does not transfer accountability and should the CRO not provide a satisfactory service the Sponsor will not be immune to sanctions by the MHRA. Compliance with Good Clinical Practice (GCP) is essential to the successful conduct of any CTIMP. Compliance with GCP principles should ensure that many of the services listed above are performed to the expected standard. The most common regulatory standards subject to MHRA inspection are detailed below with links available under the reference section of this SOP (Pharmacovigilance in CTIMPs is currently reviewed by the GCP inspectorate):

- **Good Clinical Practice (GCP)**
- **Good Clinical Practice for Clinical Laboratories**
- **Good Manufacturing Practice**

These standards are very specific and compliance should be determined by someone with experience of GCP/GMP.

3. Scope

This document applies to non-commercial CTIMPs that are sponsored by The Queen's University of Belfast. It may also apply to co-sponsored or Belfast Health and Social Care Trust sponsored Trials where funding has been awarded to the University.

There are a wide variety of agreements and contracts that can either stand alone or be incorporated as part of a larger over-arching agreement. However, the University's Research Contracts Team are best placed to advise which of the following are required.

4. Responsibilities

Chief Investigator

The Chief Investigator is responsible for highlighting the need for a contract with other parties at the earliest opportunity. He/she 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 ensure that the contract is approved by an authorised signatory (for example the Director of Research and Enterprise) prior to the research commencing.

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.

Research Contracts Team

The Research Contracts Team will be required to negotiate and subsequently produce a legally binding contract acceptable to the parties involved. 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.

Research Governance, Ethics and Integrity Team

Research Governance Team will be involved in determining the suitability of the contractor and providing guidance to both CI and Research Contracts. The consideration of suitability shall take the form of collating evidence, e.g. accreditation/certifications, inspection reports, other external quality assessments.

5. Procedure

Once funding has been awarded members of Faculty Finance, Research Contracts, Research Governance and the CI shall liaise to enable the identification of the parties involved and the contracts required for the trial. These discussions may also involve relevant external parties (e.g. N.I. CTU, BHSCT, NI Cancer Trials Unit etc).

The University's insurer for clinical trials must be informed, according to their procedures, of the proposed trial. This would normally be undertaken by the Contracts Manager responsible for the trial.

The Research Governance Team in conjunction with the CI will undertake an exercise of due diligence, advising the CI of any issues or concerns that may arise and Research Contracts of requirements needed.

The Research Contracts Office, with support from the CI and Research Governance, will draft the Trial agreements.

The draft trial agreement(s) shall be issued to the other party/parties for review. The Contracts Manager shall lead negotiations until the Trial Agreement has been agreed.

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

The Trial Agreement shall be finally approved following signature by authorised signatories in relevant parties.

6. 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.
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	The site on which trial activities are to be conducted, for example, with relevant Health Trust stating the work must be undertaken to GCP standards.
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
Co-sponsorship Agreement	An agreement to delegate responsibilities between parties.
Amendment	Where the start date, previously agreed with the funder, requires deferral.

7. References

1) Medicines for Human Use (Clinical Trials) Regulations 2004 (the Regulations) (last accessed 23 January 2017)
http://www.legislation.gov.uk/uksi/2004/1031/contents/made

2) Good Clinical Practice (GCP) MHRA Website (last accessed 23 January 2017)
http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/index.htm

3) Good Clinical Practice for Clinical Laboratories MHRA Website (last accessed 23 January 2017
https://www.gov.uk/topic/medicines-medical-devices-blood/good-practice

4) Good Manufacturing Practice MHRA Website (last accessed 23 January 2017)
https://www.gov.uk/topic/medicines-medical-devices-blood/good-practice

5) ICH GCP Guidance (last accessed 23 January 2017)
http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html