The University of Manchester

Standard Operating Procedure

Number:	UM/UoM CTU Selection /SOP21/3.0		
Title:	**Selection and Overview of a third party**		
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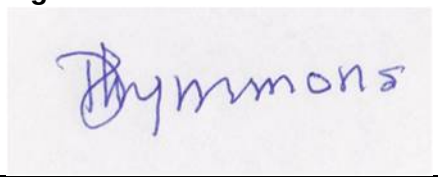
Signature: 		**Signature:** 	

Version	Date	Reason for change
2.0	**August 2016**	**Update of web links and office details**
3.0	**March 2018**	**Updated processes**

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1.0 Background

The University of Manchester, in its role as Sponsor of a clinical trial of an investigational medicinal product (CTIMP)/Medical Device, retains ultimate responsibility for the trial; therefore it is important to ensure that oversight is maintained of all vendors. The University may delegate defined functions related to such trials to a third party at the request of a Chief Investigator or research team. This will be dependent on in house expertise and resource capacity. Such activities include but are not limited to: project management, monitoring, laboratory analysis, data management, statistics and IMP management activities.

The guidance in this standard operating procedure (SOP) may therefore be used as a benchmark to assess the suitability of the third party.

2.0 Purpose

To ensure legal and GCP compliance, the University in its capacity as the Sponsor of a CTIMP/Medical Device trial and/or the Chief Investigator needs to have oversight of all functions and activities delegated to a third party. The decision to request and contract the use of a third party will be led by the Chief Investigator (CI) and the research team with the Sponsor duly informed. The University will aim to facilitate this process.

Please note: Although the Sponsor retains ultimate responsibility for the trial, all vendors must show due diligence when performing any delegated function, as they have a legal responsibility to comply with GCP, the protocol and the terms of the competent authority and favourable REC opinion.

3.0 Procedure

All proposed vendors should be highlighted to the Sponsor at the pre-funding stage, indicating the proposed activities to be delegated. Post-funding, these activities will be finalised, including a review of any potential sub-contracting activities, and the Contract's team engaged to put the relevant contracts in place. Any issues/changes to third parties/delegated activities should be reported to the Sponsor via the quarterly/monthly Clinical Trials Management Group (CTMG) reports.

This procedure only concerns studies that fall into (or potentially fall into) the category of clinical trial of an investigational medicinal product or a medical device, as defined by the Clinical Trials Regulations.

3.1 Selection and Oversight of Third Parties

The University's process for adequately assessing and documenting the suitability of a third party may vary according to the level of risk-based function and activity likely to be undertaken. The third party may be assessed for suitability using one or more of the following criteria by the Chief Investigator:

1. Positive past experience with third party
2. Recommendation of vendor from credible source (e.g. a MAHSC Partner)
3. Review of the quality management system and written procedures (including organisational charts)
4. Evidence of prior knowledge and experience of the vendor from use in other similar clinical trials
5. Completion of a pre-qualification questionnaire
6. Assessments of CVs and previous experience
7. Assessing quality systems/written procedures
8. Conducting audit of the vendor's facilities

The CTMG has Sponsor oversight of the vendor assessment process. The Chief Investigator should inform the CTMG of all external contracted activities and the basis on which the final decision, on the selection of the third party, was taken before a contract is completed. If the CTMG is not satisfied with the method used to assess the vendor, a different method must be used to provide a satisfactory level of assurance to the Sponsor.

Following this, CTMG will send a vendor assessment form to the relevant parties to confirm suitability before contract completion. This will include assessment of regulatory inspection findings, training, relevant SOPs (Quality Assurance) and further vendor details applicable to the study and contracted activities. For critical activities (e.g. manufacture/cold chain supply of IMP) not previously used by the Sponsor a further on-site audit may take place dependent on the returned vendor assessment details, the risk associated with the delegated task or for information purposes. For non-critical activities such as shipping trial document to various locations it may be more suitable to review the vendor's previous experience, obtain references and ask pertinent questions.

In addition to the University's standard vendor assessment for internal processes and systems, IMP and laboratory vendor assessment forms have been generated to assess these delegated activities specifically.

Each vendor assessment, for the activities assessed, will be valid for a period of 2 years and will be accepted for future trials requiring the same activities within this time period. Following this the vendor will be re-approached for an updated assessment if these activities are required by future trials. For on-going trials, the Sponsor will not re-approach vendors if the services supplied extend this validity period.

Example activities (not limited) requiring vendor assessments include:

- Web based platforms hosting trial content
- Lab Services
- IT Services
- Randomisation Services
- CTU activities
- IMP manufacture/supply/management/labelling
- IMP/Device stability testing

3.2 Contract

Once a third party has been selected and agreed a contract must be put in place by the University to cover the activity of the third party. The contract should contain information relating to the roles and responsibilities of the vendor, delegated functions and activities, as well as the required standards for the work to be executed over the course of the trial and how this will be monitored. The Chief Investigator must seek advice from the University's Contracts Team to ensure compliance with the all local requirements.

A copy of the signed and dated contract (and any subsequent amendments) must be filed in the trial master file.

Where GMP (Good Manufacturing Practice) activities are contracted out of the University, the Sponsor requires a technical agreement to be put in place to define the GMP responsibilities of each party. Where this, or other activities, are performed internally an internal agreement/program of work must be agreed in a written document.

If activities are being delivered as part of a service level agreement, e.g. lead pharmacist activities, a vendor assessment is not required.

Oversight of Vendor

Oversight of the third party must be maintained for the duration of the contract by the Chief Investigator in order to ensure that the vendor is meeting its contractual, legislation, good clinical practice, MHRA/Research Ethics Committee requirements. The third party will be expected to provide regular reports and communicate with the Chief Investigator regarding trial progression and important clinical related issues. All key documentation and communication with third parties should be documented in the TMF. The Chief investigator/research team or designees should provide the latest version of documents and written procedures to the 3rd party as applicable.

Where concerns arise regarding the conduct of the vendor, the University's Clinical Trials Officer (Research Governance and Integrity Team) must be informed at the earliest opportunity. The research team should also highlight any specific change or issues regarding vendors and vendor performance at their trial management group meetings and in their quarterly progress reports to the CTMG. .

As part of Sponsor oversight, the Sponsor may consider reviewing critical documents created by the vendors, for example: trial-specific instructions, pharmacy manual, laboratory manual and safety, CRF design approvals, data management and statistical plan.

4.0 References:

- Directive 2001/20/EC
- Directive 2005/28/EC
- The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 1031)
- http://www.legislation.gov.uk/uksi/2004/1031/contents/made
- The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (SI 1928) http://www.legislation.gov.uk/uksi/2006/1928/contents/made
- MHRA Good Clinical Practice Guide, 2012