MANCHESTER 1824
The University of Manchester

Standard Operating Procedure

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Title:	Vendor Selection and Oversight		
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Version	Date	Summary of Changes
2.0	August 2016	Update of web links and office details.
3.0	March 2018	Updated processes
4.0	February 2025	Periodical review and update to processes

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 (or, as also referred to in this document, a third party). The University may delegate defined functions related to such trials to a third party at the request of a Chief Investigator (CI) or research team. This will be dependent on in house expertise and resource capacity. Such activities include but are not limited to: project management, study 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 or GMP compliance, the University in its capacity as the Sponsor of a CTIMP/Medical Device trial and/or the CI 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 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, GMP, 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 UK Medicines for Human Use (Clinical Trials) Regulations 2004.

3.1 Selection and Oversight of Third Parties

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

1. Positive past experience with the third party
2. Recommendation of the vendor from credible source (e.g. a MAHSC Partner)
3. Review and assessment of the vendor's quality management system and written procedures (including organisational charts)
4. Review of previous experience / vendor CVs
5. An audit of the vendor's facilities

The CTMG has Sponsor oversight of the vendor assessment process. The CI should inform the CTMG of all external contracted activities, and the basis on which the final decision, on the selection of the vendor/s 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.

When the Sponsor is satisfied of suitability of the vendor, based on the CI recommendation, it will request completion of the UoM Vendor Assessment form, which is required to be completed for every vendor.

The CTMG will review the completed vendor assessment form. If the information received is satisfactory, the CTMG will approve the vendor. The Vendor assessment (by the sponsor) 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 be required 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 documentation 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.

Once a completed assessment has been received from the vendor, it will be reviewed by RGEIT and it will be logged with the RGEIT QA for review.

Each vendor assessment, for the activities assessed, will be valid for a period of 2 years (for CTUs 5 years registration period applies) and will be accepted for future trials requiring the same activities within this time period and added to Sponsor approved vendor list. 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, provided no organisational changes have occurred.

Examples of activities (not limited) requiring vendor assessments include:

- Web/Cloud based platforms hosting trial content
- Laboratory Services

- IT Services
- Randomisation Services
- CTU activities
- IMP/Device manufacture/supply/management/labelling
- IMP/Device combination stability testing

In instances, where a Vendor fails to comply with this SOP requirement (e.g. completion of assessment, providing supporting documentation), the CTMG will be contacted for resolution.

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 CI must seek advice from the University's Contracts Team to ensure compliance with all the 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 and agreed 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 CI in order to ensure that the vendor is meeting its contractual, legislative GCP, MHRA/Research Ethics Committee requirements. The third party will be expected to provide regular reports as necessary and communicate with the CI regarding trial progression and important clinical related issues. All key documentation and communication with third parties should be documented in the TMF. The CI/research team or designees should provide the latest version of documents and written procedures to the Vendor as and when 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 (clinicaltrials@manchester.ac.uk or medicaldevices@manchester.ac.uk). 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, safety, CRF design approvals, data management and statistical plan.

4.0 References:

- The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 1031)
- 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 https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials