SOP-QA-16 V5

Title: Selection and management of third parties

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Document History

Version	Description of update	Date Effective
4	Updated CTFG responsibilities at 2 Reference to procurement regulations at 3.1 Reference to Business Development Officer and two-yearly checks at 3.2	30-11-21
5	Updated Author Definition of a Medicinal Product at section 4	19-12-24

1. Scope

1.1 This SOP applies to Chief Investigators (CI), Sponsor staff and any researcher from University of Aberdeen (UoA) and/or NHS Grampian (NHSG) conducting a Clinical Trials of an Investigational Medicinal Product (CTIMP) or medical device clinical investigations. The SOP should also be considered best practice for any other clinical research activity.

1.2 Sponsor must be able to demonstrate oversight and approval of third parties and any sub-contracted duties. This SOP describes the procedure for issuing and completing agreements required for such projects.

1.3 A third party is considered to be any organisation, other than the UoA or NHSG, which performs a task or service as part of a research project. This includes drug and/or medical device supply providers/distributors and third party laboratory service providers. This may also include archive providers, courier services, transcription services, translation services, statistical services and data management providers sub-contracted to UoA and/or NHSG to deliver services to a specific Trial.

For the avoidance of doubt the co-sponsors, co-investigators and collaborator institutions are excluded from the definition of third party as it applies to this SOP.

2. Responsibilities

Chief Investigator (CI)	Identify appropriate third parties.
Sponsor	Facilitate appropriate oversight of contracted third parties.
Quality Assurance Manager	Undertake proportionate due diligence of third parties.
Research Development Executive	Review and execution of contracts with third parties.
CTFG	May review use and performance of contracted third parties.

3. Procedure

Trial set-up

3.1 The CI shall confirm any third parties they wish to engage at sponsor registration and risk assessment stage and, if appropriate, complete a list of all third parties using TMP-QA-74 (Third Party List) which shall be submitted to Sponsor for approval. The CI shall also confirm at sponsor registration and risk assessment stage that the budget is in place, or has been applied for, to cover all third party activities. The CI is responsible for ensuring compliance with procurement regulations.

3.2 As required, the Quality Assurance Manager shall coordinate proportionate, pre contract due diligence review on any identified third party/parties. For example: requesting copies of relevant accreditation/certification/licences (eg to manufacture/distribute MP), requesting and taking up references or remote/on-site audit. The Quality Assurance Manager shall document due diligence which may be presented to the Clinical Trials Facilitation Group (CTFG) for information and/or comment. The Quality Assurance Manager shall also liaise with the Research Development Executive as required. Third party assessments shall be repeated every two years during the active phase. Any actions arising shall be taken forward by the Quality Assurance Manager.

3.3 If an alternative third party needs to be identified, the due diligence described in 3.2 shall be repeated. The Research Development Executive in Research & Innovation (R&I) shall advise whether the funder will need to be informed.

The Research Governance Manager shall also be consulted and shall advise whether a protocol amendment is required.

3.4 Third party contracts, and any amendments, shall be managed according to SOP-QA-13 - Generation of contracts.

3.5 For third parties providing laboratory/data analysis services an Analytical Protocol (TMP-QA-18) may be completed by the CI and reviewed by the Quality Assurance Manager prior to inclusion in the contract with the third party. However, if a third party provides their own contract template the Quality Assurance Manager shall assess if this adequately addresses the management of trial samples or data, or whether a separate Analytical Protocol is also required.

3.6 The CI shall ensure that all relevant documentation is provided to the third party in a timely manner ie research protocol, approved protocol amendments, associated documentation and copies of required approvals.

3.7 The CI shall ensure that no activities are implemented by the third party until appropriate approval and contracts are in place.

Active phase management

3.8 The CI shall maintain regular contact with the third party/parties. Key correspondence and meeting minutes shall be retained in the Trial Master File (TMF).

3.9 The CI shall discuss any protocol amendments which impact the services provided by the third party with the third party and Research Governance as appropriate. Research Governance and/or CI shall advise the Research Development Executive of any amendments which may require a change to contract(s).

3.10 The CI shall notify the Research Development Executive and Quality Assurance Manager of any issues regarding the delivery of the third party services. Where necessary the Quality Assurance Manager may arrange for an audit of the service.

3.11 Where performance issues with a third party have been identified the Quality Assurance Manager shall co-ordinate the ongoing Sponsor oversight and management of the third party and shall action any identified issues as appropriate.

Project closure

3.12 Feedback on overall performance of the third party shall be collected at the monitoring close-out visit, where applicable, for future reference and be reviewed by CTFG.

4. Abbreviations and definitions

'Medicinal product' is defined in Article 1(2) of Directive 2001/83/EC.
Art. 1(2) of the Medicinal Products Directive defines "medicinal product" as follows:
"(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis."

CTFG	Clinical Trials Facilitation Group
CTIMP	Clinical Trial of Investigational Medicinal Product
R&I	Research and Innovations (UoA)
TMF	Trial Master File

5. Related documentation and references

SOP-QA-6	Study start-up
SOP-QA-7	Trial Master File
SOP-QA-13	Generation of contracts
SOP-QA-15	Management of medicinal products used in research projects
SOP-QA-19	Amendments
SOP-QA-31	Research project closure
TMP-QA-18	Analytical Protocol template
TMP-QA-74	Third Party list