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NHS Foundation Trust

SOP 700 NNUH Vendor Selection and Oversight

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
Key words:	Vendor Selection, Vendor Approval, Vendor Oversight
Name of document author:	Julie Dawson
Job title of document author:	Research Services Manager
Name of document author's Line Manager:	Jenny Longmore
Job title of author's Line Manager:	Director of Research Operations
Supported by:	Sarah Ruthven UEA
Assessed and approved by:	Julie Dawson: Research Services Manager NNUH Sarah Ruthven: Research Manager UEA
Date of approval:	25th June 2024
To be reviewed before: This document remains current after this date but will be under review	(3 years, unless legislation or process changes)
Reference and / or Trust Docs ID No:	16808
Version No:	V3

Version No:	Date of update	QPulse Change Request reference (CR no.)	Change Description	Author
3	June 2024	141	Clarification that risk assessment should be reviewed and signed off added to section 6	Julie Dawson
		153	Due diligence expanded. List of preferred suppliers clarified	Julie Dawson

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

Copies downloaded from the website are only valid on the day of downloading.

1. Contents

2. Definitions of Terms Used / Glossary

CAPA	Corrective Action and Preventive Action
CI	Chief Investigator
CSV	Computer System Validation
CV	Curriculum Vitae
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
ICH GCP	International Conference on the Harmonisation of Good Clinical Practice
ISO	International Organisation for Standardisation
NCTU	Norwich Clinical Trials Unit
NNUH	Norfolk and Norwich University Hospitals NHS Foundation Trust
QA	Quality Assurance
R&D	Research and Development
SOP	Standard Operating Procedure
TMF	Trial Master File
UEA	University of East Anglia

3. Objectives

To ensure a robust system for the selection, approval and oversight of external vendors by the NNUH.

4. Scope

Not all research activities are conducted within the Norfolk and Norwich University Hospital (NNUH) therefore a variety of service models may be required to conduct research studies. External vendors may include: Contract Research Organisations, Clinical Trials Units, Clinical Laboratories, Analytical Laboratories and Suppliers.

This SOP describes the process for selection, approval and oversight of external vendors to provide a service to support research sponsored by Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH).

A vendor is a person, organisation, facility or agency external to NNUH that provides functions, services and products for NNUH studies sponsored by NNUH.

Reference guidelines:
ICH GCP E6 (R2) guidelines and addendum, 2017.
SI 2004/103, Regulation 3.

5. Rules

- The Chief Investigator, in consultation with the Sponsor, is responsible for ensuring that appropriate processes are adopted when selecting a potential vendor

- The Sponsor must maintain a preferred Vendor/Suppliers' list – the NNUH list is available from R&D (in the SOP folder)

6. Procedure

Identification of a suitable vendor for each study

During development of the study protocol; functions, services and products which are not accessible within NNUH will be identified. Where external support is required for delivery of any aspects of the protocol, the CI shall consult with the Sponsor for advice prior to approaching suitable vendors.

It may be appropriate to short list a selection of vendors who can perform the applicable service. The short listed vendors should be prequalified to ensure the best vendor is selected. See **SOP 700 Appendix 1 Pre-qualification Questionnaire & Risk Assessment.** This should be reviewed and signed by the Chief Investigator and Sponsor Representative.

The process adopted for assessing the suitability of a vendor will be dependent on the risk of the task being delegated, what is previously known about the vendor and any previous conduct for other studies.

Where appropriate the Sponsor will consult with a procurement team to ensure their procedure is followed. Costing requirements must be considered for the subcontracted service.

Where a vigorous selection process has not been performed, this can result in non-compliance to GCP and legislation.

Business justification for use of a vendor must be documented and maintained within the Trial Master File (TMF) with the contract. See **SOP 305 Creating and Maintaining the Trial Master File or Investigator Site File**

7. Method of Assessment

The below should be considered in conjunction with **SOP 700 Appendix 1 Pre-qualification Questionnaire & Risk Assessment.**

- GCP training and awareness
- Training, CVs and experience
- GCP, GMP, GLP certification
- ISO accreditation (e.g. ISO 9001, ISO 15189)
- UKCRC Guidance for CTUs on Assessing the Suitability of Laboratories Processing Research Samples

- Obtaining suitable references
- Company history, stability and financial reports (review of the company website and Companies House if within the UK)
- Review of marketing materials (applicable to the service required)

- Previous conduct for other studies
- Adequate facility, equipment and staffing in order to meet the needs of the study
- Capability to deliver within the specified timeline

- Security of samples and data
- Assessing quality system, documented processes, SOPs
- Quality Assurance (QA) programme (if no internal QA then an audit may be required prior to approval)

8. Sponsor Involvement

The Sponsor:

- Will maintain a list of all vendors / suppliers, and therefore must be consulted on selection process
- Will help with vendor selection, issue of prequalification questionnaire
- Will initiate reassessment of vendors, via review of the risk assessment questionnaire
- May perform an audit dependent on the risk assessment outcome or lack of internal QA program
- Authorises or declines use / reuse of vendors

9. Maintaining Vendor Oversight

Oversight of a vendor is an ongoing process and can be achieved through regular email communication, progress reports, teleconference and face-to-face meetings. The CI must maintain documented evidence that this has taken place, what was discussed and record any potential issues. The CI shall also document actions, who will complete the actions and when they will be completed by. This documentation must be retained within the TMF.

The contract must describe the process for the vendor reporting issues to the CI.

If there are any compliance issues which will have an effect on the study then these must be discussed with the Sponsor, who will make an assessment of the impact for the study and may instigate an audit or a Corrective Action Preventive Action (CAPA) investigation.

It is the responsibility of the Sponsor to provide the vendor with all documentation needed to conduct the subcontracted phase of the study. Any updates to the documentation should be forwarded to the Sponsor.

The vendor must provide any updated procedure, documentation or SOP which may have an effect on the phase or service they are providing for the study to the CI. The CI should ensure that the Sponsor receives a copy. An assessment must be made by the CI to ensure the study is not impacted. The CI shall also assess if this impacts on the study protocol or contract.

10. Studies where UEA has budget responsibility

The UEA Procurement team support UEA staff with buying goods and services following UEA processes and legal regulations. Further information about the team and processes can be found on the UEA portal.

11. References and Related Documents

References
ICH GCP E6 (R2) guidelines and addendum, 2017
SI 2004/103, Regulation 3

SOP No.	SOP Title
SOP 305	Creating and Maintaining the Trial Master File or Investigators Site File
SOP 700 App 1	Pre-qualification Questionnaire & Risk Assessment

12. Approval

Author	Julie Dawson
Role	Research Services Manager
Approved & Authorised NNUH	Julie Dawson
Role	Research Services Manager
Signature	DocuSigned by: Julie Dawson 4CBAB366CF354A2...
Date	25 June 2024 | 2:04 BST
Approved & Authorised UEA	Sarah Ruthven
Role	Research Manager
Signature	DocuSigned by: Sarah Ruthven 50D5F3BEE2F04C1...
	25 June 2024 | 3:01 BST

13. Training Implication

Training Implication	**Yes**
Actions required	• Review SOP and appendix

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Pre-qualification Questionnaire & Risk Assessment

Study Title	
IRAS No.	
Protocol No.	
CI / PI	
What activities will the Vendor be performing for this trial?	
When is the service required (from – to)?	
Name of Vendor this assessment relates to	
What is the estimated cost of the service being provided?	

Risk Assessment Score		
No = 1	Yes = 0	n/a = 0

Some of the questions asked may not be appropriate for the service being provided, therefore record as not applicable and provide an explanation.

Reviewed	**Response, explanation where required (note any documentation reviewed)**	**Risk Score**
Has the Vendor has performed trial activities for another NNUH sponsored project?	**Yes / No / NA**	
If yes, were the deadlines met?	**Yes / No / NA**	
Is this a non-interventional study?	**Yes / No / NA**	
Has the Vendor demonstrated current and relevant experience?	**Yes / No / NA**	
Can the Vendor demonstrate compliance with the below Practices:		
Good Clinical Practice (GCP)	**Yes / No / NA**	
Good Manufacturing Practice (GMP)	**Yes / No / NA**	
Good Laboratory Practice (GLP)	**Yes / No / NA**	
ISO accreditation	**Yes / No / NA**	
Has the Vendor provided a	**Yes / No / NA**	

Pre-qualification Questionnaire & Risk Assessment

reference?		
Can the Vendor evidence Company stability and timely filing of financial reports?	**Yes / No / NA**	
Has the Vendor provided clear marketing materials for their products/services?	**Yes / No / NA**	
Can the Vendor meet the deadlines required?	**Yes / No / NA**	
Can Computer System Validation (CSV audit) be demonstrated? *Note: if a system is not validated then there can be no compliance claimed for the use of that system for the study.* *Off the shelf validation is not appropriate, there needs to be a full validation history*	**Yes / No / NA**	
Can security of samples and data be demonstrated?	**Yes / No / NA**	
Are SOPs/processes demonstrated?	**Yes / No / NA**	
Is there a Quality Assurance program? *Note: (if no internal QA then an audit may be required)*	**Yes / No / NA**	

Total Overall Score		
Low Risk = 0 - 9	**Medium Risk = 10 - 14**	**High Risk = +15**
Use advised	Close monitoring required	Use not advised
Acceptance	Yes ☐ No ☐	

Approval signature and date of approval must be completed by the CI / PI and R&D

Approved by	**Role**	**Signature**	**Date** (dd/mm/yy)

Contact the Research Governance Administrator if the Vendor is likely to require an Honorary Contract / Letter of Access to carry out their work