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Humber Health Partnership

Vendor Assessment SOP

Document control use only	
Reference	R&D SOP 19
Directorate / Care Group	Research & Development
Version	Version 3
Result of last review	Regulatory Changes
Issue date	27/04/2026

Author / Owner Use Only	
Group or Trust specific document	HHP (Group) – Hull University Teaching Hospitals NHS Trust, Northern Lincolnshire and Goole NHS Foundation Trust
Date approved by owner (for minor changes only outside committee)	N/A
Date approved	13/5/2026
Approving body	R&D Sponsor Oversight Group / RDI Committee
Next full review date	12/05/2029
Lead Director	Professor Sathyapalan – R&D Director James Illingworth – R&D Manager
Document type	Standard Operating Procedure
Author / Contact	Leanne Cox – R&D QA Manager
Key words	GCP, SOPs, R&D, Research & Development, Vendor Assessment

Distribution:	HHP R&D internet Click on GCP SOPs for HHP-sponsored CTIMPs https://www.hey.nhs.uk/research/researchers/gcp-sops-for-hey-sponsored-ctimps/

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AI update statement: This Standard Operating Procedure (SOP) was reviewed and updated with the assistance of an Artificial Intelligence (AI) tool. The AI output was used to support drafting and editing only; all content was verified, amended where required, and approved by the document owner/author in accordance with the Trust's document control and governance requirements.

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Working in partnership:
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This page details the version history and the main changes made for each new version.

Version Log		
Version number and date	**Author**	**Details of significant changes**
Version 1, 14.02.21	J Illingworth & S Moffat	First SOP approved by R&D Committee on 30.06.2021
Version 2, 11.04.2024	G. Constable	-Section 6: Vendor Selection and Computer System Validation (CSV), added to SOP. -R&D replaced with RDI (research development and innovation) in-line with current department name.
Version 3, 27.04.2026	L. Cox	Section 1 Explicit reference to ICH E6(R3) and its principles of risk-based quality management and oversight of delegated activities. Section 3 Clarification that vendor selection and oversight must consider critical-to-quality factors as defined in ICH E6(R3). Stronger emphasis on proportionate, risk-based decision-making. Section 4 Requirement to assess the criticality of delegated tasks. Explicit link to R3's expectation that vendor selection is proportionate to risk and potential impact on participant safety and data integrity. Section 5 Assessment of vendor data governance, including audit trails, metadata, data integrity controls, and lifecycle management. Requirement to evaluate the vendor's ability to maintain quality throughout the trial lifecycle. Section 6 Explicit reference to R3's requirements for system validation, configuration control, change management, and ongoing system oversight. Clarification that CSV must consider system updates, patches, and version changes throughout the study. Section 7 Introduction of Quality Tolerance Limits (QTLs) or performance indicators where appropriate. Requirement for contracts to reflect risk-based oversight expectations. Section 8 Requirement for ongoing risk review throughout the trial lifecycle. Expectation that oversight activities are adjusted based on emerging risks, performance issues, or system changes.

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		Section 9 Statement confirming that implementation of the SOP supports compliance with ICH E6(R3). Update from HUTH to HPP incorporating both HUTH and NLaG.

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Please note for definitions of acronyms refer to Appendix 1 of Management of SOPs. Refer to Appendix 2 of Management of SOPs for the standards to which clinical trials that investigate the safety and/or efficacy of a medicinal product are conducted.

All the HHP R&D GCP SOPs are available at:
https://www.hey.nhs.uk/research/researchers/gcp-sops-for-hey-sponsored-ctimps/

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1. Purpose

The purpose of this SOP is to describe the Sponsor/Chief Investigator/Principal Investigator responsibility of following the process to select a suitable third party vendor for a specific delegated trial activity and the contracting and oversight when the vendor has been chosen. A vendor is a person, organisation or agency external to HHP that provides functions, services or products related to the conduct of research sponsored by HHP. It does not include research collaborators or other research sites. This SOP is written in alignment with the principles of ICH GCP (R3) which emphasise risk-based quality management, proportionate oversight of delegated activities, and the requirement for sponsors to ensure that all vendors, systems, and processes contributing to clinical trials are fit for purpose and appropriately controlled.

2. Who should use this SOP

This SOP should be used by:

- All HHP RDI staff who manage the sponsorship of HHP-sponsored CTIMPs.
- Research staff involved with clinical trials sponsored by an external organisation where the sponsor has no SOP for vendor assessment. HHP R&D SOPs are defaulted to in this case.
- Research staff involved with HHP-sponsored non-CTIMPs.

3. Background

Sponsors do not perform all trial activities in-house and often use external vendors, such as Contract Research Organisations, Clinical Trials Units, laboratories, randomisation services, IMP procurement and management.

The sponsor must follow a process for the selection of a suitable vendor.
Sponsors must ensure that vendor selection and oversight follow a risk-based, quality-by-design approach. This includes evaluating the potential impact of delegated activities on participant safety, data integrity, and trial reliability. The rationale for vendor selection, the associated risks, and the controls implemented must be documented and proportionate to the criticality of the tasks being outsourced.
It should be noted that although the sponsor retains complete responsibility for the clinical trial, all vendors must show due diligence when performing delegated trial activities and all persons involved in the conduct of a clinical trial have a legal responsibility to comply with GCP, the protocol and the terms of the MHRA CTA and REC favourable opinion.
The Medicines for Human Use (Clinical Trials) Regulations 2004, Regulation 28 (1) of SI 2004/1031 and Regulation 29 of SI 2004/1031.

4. Vendor selection

The requirement for the use of external vendors must be identified during the development of the study protocol and/or grant application submission as part of the sponsor risk assessment following the CI completing the sponsorship request form. The cost of using an external vendor must also be factored into the grant application.

Where a grant application requires costings for a Clinical Trials Unit (CTU), the CTU may be chosen by the CI before any contracting takes place.

The CI must ensure appropriate processes are followed when selecting an external vendor and must liaise with the RDI Office to ensure appropriate risk assessment and contract negotiations can take place.

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RDI will ensure there is due diligence and a background check to ensure that the vendor chosen is suitable for the required task requested, is a viable vendor and is value for money before any contracting is entered into. The selection process must consider the critical-to-quality factors associated with the delegated activities. Vendors performing activities that directly affect participant safety, rights, or data integrity require enhanced scrutiny and more robust controls. The CI and RDI Office must ensure that the level of assessment is proportionate to the risk and complexity of the activity.

Where possible the CI should choose 3 vendors for price and service delivery comparison. A choice should not be made on price alone if the service is not comparable to the other vendors.

A comparison of 3 vendors is not necessary if for example the CI has used a service before and can recommend it or it is a specialist service not widely available.

The intention of the sponsor is to consolidate a list of preferred vendors however the listed vendors will still be assessed on a study by study basis.

The sponsor is ultimately responsible for all activities outsourced to an external vendor.

Where specialist services are being contracted, the CI and sponsor will liaise with the relevant expertise and support services (i.e. HHP Clinical Trials Pharmacy Team).

A risk based approach to the selection of vendors should be adopted. The CI and RDI Office will need to look at the risks associated with the tasks to be delegated as well as previous experiences and intelligence on the vendor (i.e. has the CI or Trust used the vendor in other work).

5. Vendor assessment

Vendor assessment methods include:

- Assessment questionnaires
- Assessment of CVs and previous experience
- Obtaining suitable references
- Referring to prior knowledge from use in other trials
- Assessing quality systems/written procedures/SOPs
- Assessing the vendor's data governance framework, including data integrity controls, audit trails, metadata management, and data lifecycle processes, where applicable.
- Conducting independent audits

RDI QA will send out a Vendor Assessment Questionnaire (VAQ) to the selected vendors using the appropriate questionnaire (i.e. CTU, laboratory or IMP manufacturer).

On return of the completed questionnaire and any relevant documentation (i.e. SOPs, written procedures, CVs, training records) requested by the sponsor, RDI QA will review these or ask colleagues in the relevant specialist areas to do so on their behalf.

Any anomalies will be identified and raised with the vendors.

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The Vendor assessment must evaluate not only organisational capability but also the adequacy of processes that protect participant safety, ensure data integrity, and maintain system reliability throughout the trial lifecycle.

An assessment will be considered complete when all documents requested have been received, any queries answered.

The decisions made to select a vendor must be documented and held in the TMF.

6. Vendor Selection and Computer System Validation (CSV)

When selecting vendors for clinical trials, it is essential to consider the validation requirements for computerized systems. These systems play a crucial role in capturing, processing, analysing, and reporting clinical trial data. As a sponsor, we must ensure that these systems are "fit for purpose," particularly when they impact the quality of trial data and subject safety. Properly validated systems ensure accurate data capture, processing, and reporting, minimizing the risk of protocol breaches and ensuring compliance with Good Clinical Practice (GCP) and relevant legislation. By rigorously assessing and validating vendor systems, we safeguard the integrity of clinical trial data, contributing to the overall success of our research endeavours.

All considerations should be documented with reference to specific software being used; including a reference to the version of software being considered, as these can change over time. Sponsors are required to ensure that computerised systems are validated, secure, and appropriately controlled throughout their operational lifecycle. This includes assessment of system change control, configuration management, user access controls, audit trail functionality, data backup and recovery processes, and the vendor's approach to ongoing system maintenance. Trial-specific configurations must be documented and assessed for risk and impact on data integrity. Furthermore, it is important that not only the product itself should be reviewed and validated but the any trial-specific configurations.

WI 24 provides a Computer System Validation review that should be used to document the review of software being proposed and should form part of the overall study risk assessment. The completed CSV should be signed off a reviewed within the RDI QA department (for example through Docusign) to provide a static and can be referred to throughout the study. A completed CSV report should be used to guide the study's monitoring plan in line with the overall study risk assessment.

Examples of such systems include operating system databases (such as those dedicated to the collection, processing, reporting and storing of equipment data used in a study), electronic Case Report Form (eCRF) systems, clinical trial databases, electronic data transfer tools, electronic diaries for subjects, and electronic trial master files. NB: for study databases *R&D GCP SOP 13 Data management* should be used.

Systems that are used routinely in standard of care within the trust (HHP) may not require a CSV when completing sponsorship assessments. The RDI QA department will assess these platforms on a study-by-study case.

7. Vendor contracting

After the selection of a vendor the appropriate contracts should be put in place prior to commencement of the trial. However, it is acknowledged that some trial set-up activities may

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be undertaken prior to formal execution of a contract so as not to delay study progress against milestones. In this instance, a 'letter of intent' outlining the specific set-up activities, standards to adhere to and timelines must be put in place. **To be clear, study start-up does not include shipment of IMP, trial specific screening or dosing.**

Contracts should clearly detail:

- The delegated tasks, duties and functions between the parties.
- The required standards of service.
- Any performance indicators, quality tolerance limits (QTLs), or monitoring expectations relevant to the delegated activities, proportionate to the criticality of the tasks.
- The process for further subcontracting by the vendor to ensure that subcontracting does not go ahead without the sponsor's knowledge and approval.

Contracts will be prepared according to **R&D Working Instruction 40, Contract & Agreement Preparation.** Contracts must reflect the sponsor's responsibility to maintain oversight of delegated activities and ensure that vendors have adequate resources, processes, and controls to meet regulatory and protocol requirements.

Once a contract is in place the sponsor must ensure that it remains current and that the requirements of the contract are being met by all parties.

At study set up it should be defined what will trigger the review of the contract. These triggers could be protocol amendments, updates to legislation and changes in sponsor processes.

Insufficient oversight of contracts can result in:

- No contract in place with a vendor.
- A contract in place after the study activities have begun.
- An organisation not fulfilling its contractual obligations
- Study activities continuing after the contract has expired.
- Additional study activities being undertaken without a contract amendment.

8. Sponsor Oversight of Vendor

Maintaining oversight of the vendor should be done via regular contact.
This may include:

- Emails
- Teleconferences
- Site visits
- Independent audits
- Review of agreed deadlines and contractual milestones.

The oversight must be proportionate to the activity undertaken as well as the initial and on-going risk assessment made by the sponsor. Oversight activities must be informed by ongoing risk review throughout the trial lifecycle. The sponsor should periodically reassess vendor performance, emerging risks, system changes, and any deviations from expected quality standards. Oversight should be documented in a manner that demonstrates proactive management of risks to participant safety and data integrity.

Oversight correspondence must be documented and held in the TMF.

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RDI QA must provide the vendor with all the appropriate documentation to enable them to provide the service they are contracted to do (i.e. copies of the protocol and any subsequent amended protocol, updated SmPCs).

A clear 'two-way' communication and update process should be established so that any changes originating from both parties regarding the delivery, management or oversight can be risk assessed and formally agreed.

An escalation process must be in place to ensure any identified non-compliance or performance issues can be assessed and dealt with.

9. Implementation

Implementation of this SOP will conform to the process outlined in R&D SOP 01 Management of SOPs. This SOP supports compliance with ICH E6(R3) by ensuring that vendor selection, assessment, contracting, and oversight are conducted using a risk-based, quality-focused approach.