

2019

HEALTH+MEDICAL RESEARCH

Sub-contracting external vendors

Standard Operating Procedure



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1. Purpose

To describe the process for the approval of external third-party suppliers (vendors) contracted by a trial site. To ensure that sites conducting clinical trials take appropriate account of the Guidelines for Good Clinical Practice based on sponsor requirements¹.

2. Scope

All clinical trials (except Teletrials)² conducted at NSW Public Health Organisations.

3. Applicable to

The principal investigator (PI) and all site staff.

Relevant support department staff.

The Research Office.

4. Definitions

Refer to SOP-G-01: Glossary of terms.

5. Background

ICH GCP requires an investigator or institution that retains the services of an individual or party to ensure the individual or party is qualified and where appropriate, credentialed to perform those trial-related activities. For example, this may occur when the organisation's local support departments cannot undertake a particular investigation required by the protocol. All vendors contracted as third-party suppliers of clinical trial services (e.g. IMP shipment, eye tests, laboratory or radiology services, participant identification services) should be assessed as appropriately qualified and credentialed and as having sufficient knowledge and experience to perform their contractual obligations.

If the PI identifies a need for an external vendor, they should follow the organisation's process for procurement of vendors. The service level agreement should be signed by someone with delegated authority to sign on behalf of the organisation (rather than the PI or unit manager). Once a vendor has been selected, a contract/service level agreement between the organisation and the vendor must be negotiated and executed. For service providers that are used frequently, this is likely to take the form of an overarching agreement with appendices for individual trials.

6. Procedure

Principal Investigator (PI)

Ensure that no activities are implemented by the third party until appropriate approval and contracts/service level agreements are in place.

Ensure vendors are provided with all relevant materials to undertake their contracted activities (e.g. trial protocol, protocol amendments, copies of relevant site standard operating procedures).

PI or delegate

Maintain regular contact and oversight of vendors and ensure relevant correspondence and meeting minutes are filed in the investigator site file (ISF).

Research Office

Be satisfied that all vendors are qualified and appropriately credentialed to perform their trial-related activities.

7. References

[ICH GCP \(E6 R2\): Good Clinical Practice Guidelines – Annotated by the TGA](#)

8. Associated documents

None

¹ All trials must comply with the principles of GCP (Section 2 of ICH GCP (E6 R2) or Clause 4 of ISO 14155) however sponsors submitting data to regulatory authorities will normally require full compliance with ICH GCP (E6 R2) or ISO 14155 GCP Guidelines.

² NSW Health have published an annotated version of these SOPs for sites utilising a Teletrials model.