

2020

HEALTH+MEDICAL RESEARCH

—
**Sub-contracting
external vendors**

Standard Operating Procedure
involving Teletrials



NSW Health

100 Christie Street

St Leonards NSW 2065

(02) 9391 9228

www.health.nsw.gov.au

www.medicalresearch.nsw.gov.au

The Ministry of Health has developed these resources as a guide to support public health organisations in developing local governance around tele-trials. The resources should not be relied upon as a complete summary of obligations on public health organisations in relation to clinical trials and are not intended to circumvent clinical judgment or replace locally developed clinical trials policies. Public health organisations are encouraged to seek legal or other advice if there is any uncertainty around compliance with clinical trials requirements.

This work is copyright. It may be reproduced in whole or in part for study or training purposes subject to the inclusion of an acknowledgement of the source. It may not be reproduced for commercial usage or sale. Reproduction for purposes other than those indicated above requires written permission from the NSW Ministry of Health.

© NSW Ministry of Health 2020

Further copies of this document can be downloaded from the NSW Health website:

www.medicalresearch.nsw.gov.au/clinical-trial-toolkit

SHPN: (OHMR) 200173-3

Document details

Document ID:	TT SITE SOP-QA-03
Version:	1.0
Effective date:	09/04/2020
Review date:	09/04/2021

Document approval

Name	Position	Signature	Date
Dr Antonio Penna	Executive Director, Office for Health and Medical Research		09/04/2020

Document history

Version number	Effective date	Details of editions
1.0	9 April 2020	New

1. Purpose

To describe the process for the approval of external third-party suppliers (vendors) contracted by a Primary Site involved in a Teletrial. To ensure that sites conducting clinical trials involving therapeutic goods take appropriate account of the Guidelines for Good Clinical Practice based on sponsor requirements¹.

2. Scope

All clinical trials conducted at NSW Public Health Organisations involving Teletrial sites.

3. Applicable to

The principal investigator (PI) and all staff involved in clinical trial.

Relevant support department staff.

Research Offices.

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.



Where a Satellite Site requires the services of a third-party provider, the process for contracting that provider should be outlined in the Supervision Plan or other agreement. If the same third-party provider is used by more than one site (e.g. by both the Primary Site and a Satellite Site) a single service level agreement may be used to cover the sites.

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).

Relevant 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.