

2019

HEALTH+MEDICAL RESEARCH

Trial feasibility and start-up

Standard Operating Procedure



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The NSW Ministry of Health has developed these resources as a guide to support public health organisations in developing local governance around clinical 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.

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Further copies of this document can be downloaded from the Clinical Trial Toolkit webpage:


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SHPN: (OHMR) 190585-4

Document details

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|-----------------|----------------|
| Document ID: | SITE SOP-TC-01 |
| Version: | 1.0 |
| Effective date: | 01/10/2019 |
| Review date: | 01/10/2020 |

Document approval

| Name | Position | Signature | Date |
|------------------|--|--|------------|
| Dr Antonio Penna | Executive Director, Office for Health and Medical Research |  | 01/10/2019 |
| | | | |

Document history

| Version number | Effective date | Details of editions |
|----------------|----------------|---------------------|
| 1.0 | 1 October 2019 | New |
| | | |

1. Purpose

To describe the steps for undertaking clinical trial feasibility and start-up procedures. 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

- Principal Investigator (PI) and all staff involved in a clinical trial
- Relevant support department staff
- Research Office

4. Definitions

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

5. Background

ICH GCP requires the PI to demonstrate a potential for recruiting the required number of suitable participants within the agreed timeframe. In addition, ICH GCP requires the PI to confirm that they have sufficient time and an adequate number of qualified staff and facilities to complete the trial properly and safely.

Robust feasibility and study start-up processes enable the trial sponsor to verify that the site is an appropriate location at which to conduct the trial and are an essential part of ensuring the site delivers high-quality data and meets NSW recruitment metrics. The process includes an assessment of:

- **The strategic fit to the organisation** – To determine whether the interventions/ comparators are considered optimal standard of care, clinical equipoise is in place, the trial is considered clinically important by the clinicians involved, the local patient population is not over-researched, the impact of the local patient pathway has been assessed, the trial sufficiently aligns with the Organisation's clinical services plans.
- **Recruitment feasibility*** – To determine (e.g. through database searches) that the study population exists in great enough numbers to meet

recruitment targets based on a review of barriers to recruitment and likely strike rate.

Where relevant, recruitment planning to identify the strategies and resources required to recruit participants from other sources (e.g. social media, radio adverts) should be undertaken.

- **Capacity and capability** – To confirm all operational requirements (e.g. additional investigations, out of hours sample collection) are feasible, and that supporting departments (e.g. pharmacy, radiology, labs, finance, contracts) can manage any additional workload.

** Decisions may be made to support trials involving rare diseases where recruitment cannot be predicted.*

Following confirmation of site selection, study start-up arrangements can begin, including the collection of:

- documentation to confirm trial team qualifications and declarations (e.g. CVs, GCP certificates and if applicable and where applicable, financial disclosure and 1572 forms).
- any requested documentation from site-specific vendors (e.g. accreditation as listed on a 1572).
- other requested documents (e.g. documentation confirming GCP compliance of databases/electronic medical records, requirements for the exposure of humans to ionising radiation).
- Study costing information to enable finalisation of contracts or agreements.

Completion of all governance activities is managed in accordance with Policy Directive [PD2010_056]: Research – Authorisation to Commence Human Research in NSW Public Health Organisations.

6. Procedure

PI or delegate

If requested by the sponsor, complete the sponsor's pre-qualification process including where requested, the signing of the Confidential Disclosure Agreement to enable the release of the protocol to the site.

Follow the sponsor's site selection process, promptly providing all necessary documentation on request.

Discuss the trial with site representatives as required by local policy (e.g. the head of department/clinical

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.

service lead/Director of Research) or if convened by the Department/Organisation, at meeting to determine whether the trial should be conducted at the site.

If the sponsor decides not to select the site, request feedback to inform future process improvement.

Discuss any operational difficulties and possible resolutions (e.g. implementation of a protocol amendment) with the sponsor. Where insurmountable issues remain that jeopardise the successful delivery of the trial, confirm with the sponsor the site's decision not to proceed with the trial.

If the sponsor confirms the site has been selected, inform the Research Office as soon as possible.

Work closely with the sponsor and any organisational staff supporting study start-up to complete all trial start-up arrangements.

Declare any conflicts of interest in writing to the Research Office and any payments received from parties concerning the study.

Ensure all relevant staff attend the sponsor's study initiation. This meeting should be scheduled once:

- Ethics and governance approvals are in place and if applicable, the Clinical Trial Notification/Exemption process has been completed.
- All supplies required to conduct the trials have been delivered to the site.

Research Office

Develop processes to ensure that study start-up procedures are facilitated.

Use metrics to identify any bottlenecks in study start-up to support the implementation of continuous process improvement.

7. References

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

[Policy Directive \[PD2010_056\]: Research – Authorisation to Commence Human Research in NSW Public Health Organisations](#)

8. Associated documents

Initiation checklist – available in the Standard Operating Procedures templates [zip file](#)