


STANDARD OPERATING PROCEDURE (SOP)

TITLE: CLINICAL TRIAL FEASIBILITY AND START-UP



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1. PURPOSE:

The purpose of this SOP is to describe the procedure of clinical trial feasibility and start-up undertaken at Epworth HealthCare and to ensure:

- All relevant departments (internal and external) are consulted and can support the project.
- The proposed trials are a strategic fit and aligned with Epworth values.
- Research projects have the best possible outcome in terms of recruitment, patient safety, budget and time frames.

2. SCOPE:

All clinical trials to be conducted at Epworth.

3. APPLICABILITY:

This applies to all Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) and to all relevant external persons or parties proposing to engage in the research activity at Epworth.

4. GLOSSARY OF TERMS:

Please refer to Epworth SOP Glossary of Terms (see Related Documents).

5. PROCEDURE:

The PI must be familiar with all regulatory and institutional requirements as per the Research Policy¹ and Research Handbook².

5.1 Feasibility

- Feasibilities can only proceed with a nominated coordinating Principal Investigator (PI) who will take on responsibility for the feasibility and subsequent conduct at Epworth.
- The PI, if agreeing to lead the trial, will:
 - Review the clinical trial including all necessary staff to assist as required
 - Discuss the trial at their earliest convenience with the relevant Divisional Director of Medical Services (DMS) and/or Director of Clinical Services (DCS) to establish clinical safety and practice can be met
 - Discuss the trial at their earliest convenience with the Research Operations Manager (ROM) to establish if the resourcing and operational requirements of the trial can be met
 - Identify current services and additional services/supplies required to facilitate protocol requirements and confirm support from all relevant departments/divisions in terms of resourcing, safety and strategic fit (as per Epworth Research Policy and Epworth Research Handbook)

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- Confirm support from third party providers where applicable in line with SOP-QA-04: Vendor Assurance
- Following input from all relevant departments the PI will complete and submit the feasibility questionnaire in collaboration with the relevant trial staff. Where possible standardised answers should be provided.
- The PI is responsible for all communication with the Sponsor and to ensure that the Research Operation Manager (ROM) is informed of the decision to proceed or not.
- The PI/Clinical Trial Coordinator (CTC) should ensure a completed copy of the Feasibility questionnaire is provided to the ROM.
- The PI/CTC will maintain a record of all feasibilities and ensure these are made available to the ROM or Research Quality Coordinator (RQC) upon request.
- The ROM and RQC will collate all information provided, including decisions to proceed or not, in a central Clinical Trial Feasibility Register (CTPR).

5.2 Pre-Site Selection Visit

- Once a clinical trial has been deemed feasible a site qualification visit may be arranged to include the Sponsor/contract research organisation (CRO), PI and Epworth. The purpose of this is to evaluate the site's ability to perform the clinical trial in accordance with the study design and protocol.
- Attendees may include sponsor/CRO representative(s), PI, sub-investigators or Epworth study team, as indicated and available.
- A facility tour is conducted during the qualification visit to confirm required equipment, space and services are satisfactory to facilitate the clinical trial protocol and all storage of clinical trial supplies and materials are secure with limited access.
- The Sponsor/CRO representative should provide copies of relevant clinical trial materials to attendees prior to the visit.
- The PI will confirm the ability to recruit the proposed number of participants within the protocol specified time frame.
- On request, Epworth will provide the Sponsor/CRO representative with appropriate documentation to support site selection.
- Where the Sponsor advises that Epworth is not selected, the PI must inform the ROM so this decision can be recorded in the CTPR.

5.3 Site Selection Follow-Up

- Where the Sponsor confirms Epworth is selected as a site, the PI must inform the ROM of this decision.
- The PI/study team is responsible for requesting supporting documentation from the Sponsor including, but not limited to, the protocol, investigator's brochure, pharmacy manual, laboratory manual, imaging manual, and data completion guidelines.
- The PI/ study team will review all documentation internally to assess operational logistics and planning, and confirm continued support from the relevant departments/divisions
- The PI/study team will ensure the relevant manuals and documents are provided to third party providers such as pharmacy and pathology to ascertain if the departments can provide the services required for the conduct of the trial (see also SOP-QA-04: Vendor Assurance).
- Where Cancer Trials Australia (CTA) are potentially involved the PI/study team has a responsibility to notify them of the proposed study via the Study Start-Up Manager (SUM) in accordance with SOP-TM-15: Working with Cancer Trials Australia.
- When service provision from the third parties has been confirmed, the study team will advise the ROM that the trial is operationally feasible to conduct at Epworth.
- The PI or delegate must register the project with the RDGU upon confirmation of site selection (see SOP-RG-01: Research Governance).
- The PI must inform the Sponsor if it is decided that the trial will not proceed at Epworth and the decision logged on the CTPR.

5.4 Clinical Trial Start-Up

Once feasibility and site selection is completed the clinical trial start-up process will commence.

- It is the responsibility of the PI to ensure that appropriate governance approvals, and regulatory notifications/approvals are in place before recruitment commences (see SOP-RG-01: Research Governance).
- Where relevant, the PI/study team will notify the CTA SSUM and ESS that the ethics and governance submission process can begin (see SOP-TM-15: Working with the CTA).
- An Investigator Site File (ISF) must be established before recruitment begins (see SOP-TM-02 Investigator Site File and Essential Documents for further information). It is the responsibility of the PI to ensure that all required documents are collected and filed in the ISF.

5.6 Site Initiation / Trial Start-Up Meeting

- It is the PIs responsibility to ensure that there is a trial start-up meeting. The trial start up meeting should be arranged for all research staff involved, including supporting services as appropriate, once all the agreements and approvals are in place.

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- The meeting should cover a review of the trial protocol and all relevant documentation and trial specific SOPs, with particular attention paid to GCP compliance where appropriate. All relevant training logs must be completed and signed by all personnel before the trial commences.
- The PI should document on the trial delegation log the members of the research team and the trial duties that they may carry out. In addition to signing the trial delegation log, each member of the research team should be able to demonstrate that they are qualified by training and experience to perform their designated tasks.
- For all trials conducted at Epworth, the PI and all other members of the research team should hold evidence of attendance at a GCP course within the last 3 years (see SOP-QA-01: Documentation of Qualifications and Training Records, and SOP-RG-04 Researcher Credentialing for further guidance). If individuals have not had training or it has expired (beyond 3 years since their last course) training must be attended prior to their involvement in the trial.
- The PI is responsible for ensuring that all of the practical elements required for the trial are in place prior to commencing recruitment.

6. REFERENCES:

1. [Epworth Research Policy](#)
2. [Epworth Research Handbook](#)

7. RELATED DOCUMENTS:

- SOP-QA-01: Documentation of Qualifications and Training Records
- SOP-QA-04: Vendor Assurance
- SOP-RG-01: Research Governance
- SOP-RG-04: Researcher Credentialing
- SOP-TM-02: Investigator Site File and Essential Documents
- SOP-TM-15: Working with Cancer Trials Australia
- SOP-Glossary-of-Terms

8. VERSION CONTROL

Document History	
Version	Summary of Changes
1.0	N/A – First Issue
2.0	Section 5.1 updated to further clarify how the CTPR will be maintained. Minor grammatical and formatting corrections throughout.
3.0	Section 5.3 Feasibility Follow-up: section renamed to ‘Site Selection Follow-up’ and further clarification provided regarding PI/study team responsibilities after site selection.

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Additional clarification CTA to be notified of potential study after site selection (rather than during feasibility).

9. APPENDIX

N/A