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Budgets and Contracts

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1.0 Introduction / Background

There are several policies and guidelines for clinical trial financial and contractual compliance that need to be adhered to when budgeting and contracting is concerned.

The International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines requires that there is evidence prior to the clinical trial being initiated that there are financial arrangements documented between the Sponsor and the Investigator/ Institution.

The National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research also defines the requirements for adequate finances to monitor the clinical trials, reimbursement of clinical trial participants and the requirements for review of financial arrangements by the Human Research Ethics Committee (HREC) and Research Governance Office (RGO).

New South Wales (NSW) Health policies also outline the responsivities in contracting for PD2023_017 Research Agreements in NSW Health Organisations and PD2011_006 Clinical Trials - Insurance and Indemnity.

2.0 Objective

To describe the procedure for the creating a budget for clinical trials and the development, approval and management of contracts for these clinical trials.

3.0 Scope

This SOP applies to all staff involved in clinical trials at South Western Sydney Local Health District (SWSLHD) and the Ingham Institute.

4.0 Ownership and Responsibility

The Principal Investigator (PI) or delegate is responsible for determining the budget for each clinical trial and providing evidence to the RGO that there are sufficient resources and funds to conduct the clinical trials. Where the budget provided by the Sponsor is not covering the

resourcing and financial costs of the clinical trial the PI must provide evidence of where these funds or in-kind work will be paid from e.g. trust funds.

All contracts for clinical trials being conducted in SWSLHD are to be with the LHD and not the individual PI. The details for contracts can be found on the Ethics Committee website: https://www.swslhd.health.nsw.gov.au/ethics/

The Ingham Institute may contract any clinical trials for work conducted outside of the SWSLHD jurisdiction. The details for contracts can be found on the website: http://www.thespot.inghaminstitute.org.au/clinicaltrials

This applies to Industry Sponsored, Collaborative Groups and Investigator initiated clinical trials.

5.0 Associate Documents

SOP_CTSU_01 Risk Assessment for Clinical Trials

SOP_CTSU_02 Investigator Responsibilities

SOP_CTSU_17 Data Recording - source data, case report forms, record keeping and archiving

6.0 Procedure

6.1 Budgets

The PI should obtain the budget template from the Sponsor as soon as possible after site selection has been confirmed. All clinical trials should have a budget created specifically for the facility that the clinical trials is being conducted in.

The PI or delegate will compare the protocol requirements with the budget template provided by the Sponsor.

Site specific budgets need to be developed and shared with Sponsor for consideration. The PI or delegates can use the sponsor provided template to incorporate all site fees.

A site schedule of fees is available at the beginning of each year to be used for Commercial Sponsors. All clinical trials must have a 30% overhead cost included in the budget.

Budget specific items that need to be considered:

- The level of risk associated with the clinical trial. For more information refer to SOP_CTSU_01 Risk Assessment for Clinical Trials
- Identifying the standard of care procedures. These must be identified in the budget that is being submitted as part of the Site Specific Assessment (SSA).
- Identifying all resources needed to conduct the trial.
- Identifying supporting departments and service providers. Establishing their relevant fees and contracts needed.
- Assessing the levels of complexities in conducting the trials as per the protocol requirements.
- Appropriate recruitment strategies will need be considered.
- All activities will need to be costed for including pre-screening activities. Unless negotiated to be covered as part of standard of care.
- Thorough review of the schedule of activities and ensuring that all activities are captured in the budget.
- Adequate patient reimbursements will need to be included in the budget.

The Clinical Trial Support Unit has extensive experience in budgets and contracts negotiations and can be consulted at any time.

The PI or delegate will send the revised site specific budget back to the Sponsor for review further negotiation and approval. Further explanation and or documentation may be required by the Sponsor to assist with the negotiations. The Clinical Trials Unit can provide justification on site schedule of fees and can provide assistance in negotiations.

6.2 Contracts

The NSW Health Policy PD2023_017 Research Agreements in NSW Health Organisations outlines the requirements for Clinical Trial Research Agreements (CTRA) in SWSLHD. The Ingham Institute endorses this policy with the exclusion of the requirement for the Eastern Seaboard Committee and the RGO reviews.

The PI or delegate should review that the correct version of the Medicines Australia CTRA or SWSLHD Research Collaborative Agreement has been used for the clinical trial. If neither of

these two agreements have been provided by the Sponsor the PI or delegate should consult with the RGO and/or Clinical Trials Support Unit. The review should also include:

- The legal address and ABN is correct.
- All sections of the CTRA have been completed. Do not leave any blanks and use "Not Applicable" where required.
- The Schedule match what has been agreed with the Sponsor for the budget.
- Future date is indicated for recruitment.
- The contact details on the front page are up to date and accurate.

Investigators cannot directly enter a contract with the Sponsor on behalf of the SWSLHD. All contracts including Non-Disclosure and or Confidential Agreements (NDA/CDA) must be established between SWSLHD and the Sponsor.

6.3 Amendments

The PI should assess the impact of a protocol amendment on the operations of the clinical trial and amend the budget and CTRA accordingly. The budget should be reviewed, updated and submitted to the Sponsor for approval as described in Section 6.1.

The CTRA should be updated and submitted to the RGO or the Ingham Institute for review and approval after the protocol amendment has been approved by the Human Research Ethics Committee (HREC).

6.4 CTRA tracking

The PI or delegate should immediately notify the RGO and Clinical trials Support Unit if there have been any of the following:

- Deviations from the terms in the CTRA
- Serious breaches reported
- Audits or Regulatory inspection notifications

The PI or delegate must track the payments made in accordance with the CTRA to verify all remuneration has been received from the Sponsor. A full reconciliation must be completed prior to the archiving of the clinical trial. See SOP_CTSU_17 Data Recording - source data, case report forms, record keeping and archiving.

7.0 References

ICH GCP (E6 R2): Good Clinical Practice Guidelines - Annotated by TGA

National Statement on Ethical Conduct in Human Research (2023)

Australian Code for the Responsible Conduct of Research (2018)

PD2023_017 Research Agreements in NSW Health Organisations
PD2011_006 Insurance and Indemnity

8.0 Amendment History

Version	Date	Amended by	Details of Amendment
2.0	22-Feb-2022	Erfan Jaberiyanfar	• Updated list of associated documents. • 6.1 – Updated to indicate additional steps • Remove PD2018_016, as no longer required for objective • Grammatical changes • Updates to points of contact and reference. • Update of reference links

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