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# Clinical trial budgets: Guidance for anaesthesia investigators and research departments

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## Purpose of document:

This guide aims to equip research coordinators, trial managers, finance officers, and principal investigators (PIs) with strategies to develop realistic trial budgets, manage and track costs over time, negotiate contract terms with commercial sponsors and to plan for contingencies and amendments. This is based on an ANZCA CTN and Anaesthesia Research Coordinators Network (ARCN) Educational session led by Carolyn Stewart, Business and Operations Manager of the Melbourne Children's Trials Centre (MCTC).

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The development of the Anaesthesia Research Coordinator Network (ARCN) and ANZCA CTN toolkit is being led by the CTN office team, in collaboration with the ARCN sub-committee and the CTN executive. We gratefully acknowledge the contributions of the ANZCA CTN members, CTN office, ARCN sub-committee, and CTN executive in the creation, preparation, development, and review of this document.

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# Clinical trial budgets: Guidance for anaesthesia investigators and research departments

## Introduction

This document draws on information based on ANZCA CTN and Anaesthesia Research Co-ordinators Network (ARCN) educational session led by Carolyn Stewart, Business and Operations Manager of the Melbourne Children's Trials Centre (MCTC). It provides guidance on budgeting for both commercially sponsored and investigator-initiated clinical trials (ITTs), with a strong focus on sustainability, financial transparency, and effective negotiation.

The content is designed for research co-ordinators, trial managers, finance officers, and principal investigators (PIs) to equip them with comprehensive knowledge, tools, and strategies to:

- Develop realistic trial budgets.
- Manage and track costs over time.
- Negotiate contract terms with commercial sponsors.
- Plan for contingencies and amendments.

## Section 1: Foundations of clinical trial budgeting

### 1.1 Defining a clinical trial budget

A clinical trial budget is a structured financial blueprint that outlines all anticipated revenues and expenses associated with executing a clinical trial. A well-crafted budget ensures:

- Full cost recovery for all services and staff.
- Accountability and financial oversight.
- Transparency in grant or sponsor negotiations.
- Sustained financial health of research units.

### 1.2 Key financial terms and concepts

Understanding these terms is essential for navigating budgeting:

- Income/revenue: The total funding or payments received for performing trial-related tasks.
- Fixed costs: Costs that do not fluctuate based on trial activity (e.g., rent, staff training, insurance, stationary, laptops).
- Variable costs: Costs dependent on patient volume or visit frequency (e.g., pathology, imaging, nurse time, equipment and servicing of equipment).
- Overhead/infrastructure costs: Applied percentage to recover costs related to administration, use of facilities, and research governance (typically 20–30%).
- Salary on-costs: Employer expenses including superannuation, payroll tax, leave entitlements.
- Pass-through costs: Direct expenses for participant-specific needs such as travel, parking, or accommodation.
- Invoiceable items: Ad hoc services such as unscheduled visits, screen failures, or courier fees.

## Section 2: Building a trial budget from the ground up

### 2.1 Preparing internally

Start by reviewing the study protocol and identifying the following:

- Schedule of assessments for each participant visit.
- Time requirements for all study-related procedures.
- Staff involvement (e.g., investigators, research nurses, data entry personnel).

Create a budget workbook that includes:

- Participant-level costing.
- Start-up and close-out fees.
- Institutional overhead and salary on-costs.

### 2.2 Identifying fixed and variable costs

*Examples of fixed costs:*

- Site initiation meeting.
- Site start up meeting.
- Ethics and governance submission.
- Trial documentation preparation.
- Investigator meetings.
- Pharmacy costs.

*Examples of Variable Costs:*

- Participant visits (screening, enrolment, follow-up, data cleaning and queries).
- Blood collection and analysis.
- Clinical assessments (e.g., Electrocardiogram (ECG), spirometry).
- Study drug dispensing.
- Nursing support per visit.
- Drug manufacturing.
- If supplied equipment for a trial, clarify who pays for servicing etc.

### 2.3 Estimating pass-through expenses

- Travel reimbursements for participants (local or regional).
- Hospital stays for participants (overnight or day admission).
- Courier and study documents archival costs.
- Specialised procedures or imaging at third-party facilities.

## Section 3: Constructing a comparative budget

### 3.1 Why prepare a comparative budget?

Commercial sponsors typically submit pre-populated budget templates. Creating your own version first allows you to:

- Validate whether proposed reimbursement covers actual costs.
- Identify discrepancies in hourly rates, visit effort, or pass-through assumptions.
- Negotiate from an informed position.

### 3.2 Tools and data sources to use when creating your budget

- Australian Medicare Benefits Schedule (MBS) for procedure pricing.
- Australian Medical Association (AMA) fee schedules for clinician time.
- Institutional pay scales for support staff salaries.

- Published cost guides such as NHMRC's Independent Health and Aged Care Pricing Authority (IHPA) document
- Quotes from institutions departments e.g. pharmacy, pathology, biomedical engineering.

### 3.3 Calculating staff time and visit duration

Estimate:

- Phone contact pre-visit and post-visit (allow 30 mins per contact point).
- Pre-visit preparation (1–2 hours).
- In-visit time (up to a full day for enrolment visits).
- Post-visit data entry and Adverse Event (AE) follow-up.

Use time-based or FTE costing to calculate.

Some grants require FTE costing or hourly costing.

**Time based costing:**

Visit Cost = (Time for Nurse x Hourly Rate) + (Time for PI x Hourly Rate) + Consumables + Department Charges + Overhead.

**FTE costing for staff:**

For example if it is determined that each patient takes up 0.5 FTE for a week and it is estimated that you have 2 patients a week, you would need to have 1 FTE in staffing to accommodate this.

## Section 4: Navigating the contracting process

### 4.1 Overview of Clinical Trial Research Agreements (CTRA)

In Australia, CTRAs follow standard templates. Key schedules include:

- Schedule 1: Trial details and responsibilities.
- Schedule 2: Detailed budget and payment milestones.
- Schedule 7: Any modifications to the core agreement. Note: Supporting Departments may need to review the CTRA early too e.g. Pharmacy, pathology as they might have changes to request to this too.

### 4.2 Critical clauses to review

- Participant recruitment targets: Ensure feasible and non-penalising numbers.
- Payment frequency: Quarterly is standard; avoid lengthy delays between visit and payment.
- Screen failure reimbursement: Define allowable ratio (e.g., 3 screen fails per enrolment).
- Startup fees: Paid upon contract execution—not delayed until enrolment begins.
- Governance fees: Ensure costs for governance amendments are included.
- Withholding clauses: Avoid or tightly control timing and percentage (e.g., 10% upon database lock).

### 4.3 Cancellation clauses and contingency agreements

Include cancellation fees (e.g., $2,500–$5,000) to recover setup time if a sponsor withdraws before ethics approval or site activation.

## Section 5: Budget negotiation tips

### 5.1 General principles

- Know the break-even point: Minimum number of patients needed to cover all site costs.
- Justify your costs: Reference MBS, AMA, institutional pay scales.
- Do not accept lowball estimates or generalised "fair market value" claims without documentation.

### 5.2 Know your leverage

- Highly qualified PIs give your site negotiating power.
- Access to unique patient populations (e.g., paediatrics) adds strategic value.
- Previous performance metrics (e.g., recruitment speed) can strengthen your position.

### 5.3 Long-term trials

- Budget for inflation and wage growth.
- Include clauses for contract and budget amendments at protocol version changes.
- Monitor actual cost recovery annually.

A reasonable budget allocation for inflation and wage growth in investigator-led trials in Australia generally falls within the range of 3% to 5% per annum.

This estimate covers:

- CPI (Consumer Price Index)–linked inflationary increases for general trial costs.
- Annual wage indexation based on enterprise bargaining agreements (EBAs) in the public health sector or national wage trends.
- Institutional escalation policies (some sites mandate 2–4% yearly increases on research costs in multi-year contracts).

## Section 6: Tracking payments and financial oversight

### 6.1 Best practice for payment monitoring

- Assign unique cost centres per trial.
- Create study-specific spreadsheets to log:
    - Participant visits.
    - Invoice dates and amounts.
    - Payments received vs. expected.

### 6.2 Sponsor payment reconciliation

Request regular payment summaries from sponsors and cross-check against internal visit logs and pass-through invoice submissions.

### 6.3 Institutional systems

- Advocate for integration of trial finance with governance records
- Engage the finance team to produce monthly balance reports
- Have quarterly meetings with the financial team to ensure fiscal responsibility
- Identify surplus/deficit trends to inform future budget development.

## Section 7: Investigator-Initiated Trials (IITs)

### 7.1 Building budgets for IITs

- Align trial costs with available grant funding
- Include all staff Full Time Equivalents (FTE) and service fees
- Ensure early consultation with finance and governance

*Note: Be realistic with the time required for each timepoint of the trial when calculating how much FTE is required.*

### 7.2 Contingency and ethics requirements

- Ethics committees often require justification of financial sustainability.
- Track burn rate regularly; adjust enrolment targets or staffing if needed.
- Plan for potential re-budgeting with amendments.

## Section 8: Contingency planning and risk mitigation

### 8.1 Common financial disruptions

- If new staff are being recruited or hired this process to recruit and onboard can take a long time.
- COVID-19 (or other) restrictions or hospital access limits.
- Suspension of theatre lists, quiet periods i.e Christmas/summer.
- Cyberattacks or data loss.
- Recruitment delays (drug supply issues).
- Sponsor site closure.

### 8.2 Strategies for preparedness

- Understand minimum patient numbers for viability.
- Establish costed cancellation or deferral clauses.
- Include business continuity planning in hospital-wide frameworks.
- Advocate for organisational support if system-wide events occur.

## Section 9: Resources and templates

### 9.1 Tools and links

- MCRI Launching Pad: Templates for budgeting, invoices, and sponsor communication.
- MCRI Setting up a research Budget Guidance Document.
- NSW Health Budget Template: Structured costing for public health research.
- MBS Schedule and AMA Rates: National references for fair pricing.
- NHMRC Costing Document (IHPA): Framework for standardised clinical trial cost items.

### 9.2 Templates provided

- Costed schedule of assessments.
- Budget calculation workbook.
- Payment tracking spreadsheet.
- Template for CTRA Amendment Request.
- Contingency fee agreement (Startup Cancellation).

## Conclusion and key recommendations

Clinical trial budgeting is not simply about cost recovery—it's about protecting the sustainability of research operations and ensuring fair compensation for complex and high-risk work.

## Top 10 recommendations:

1. Develop your own budget before reviewing the sponsor's.
2. Document and justify every line item.
3. Include overhead and on-costs systematically.
4. Request cancellation and screen failure protections in the contract.
5. Renegotiate when protocol amendments change workload.
6. Use institutional references (MBS, AMA, pay scales).
7. Track all payments in real-time via cost centres and spreadsheets.
8. Request regular sponsor payment logs for verification.
9. Plan for study duration beyond 2 years with escalation clauses.
10. Share and learn from peer templates, resources, and finance teams.

Need help? Contact ANZCA CTN ctn@anzca.edu.au or access the MCRI Launching Pad for templates and support.