Factsheet: Tips for Completing a Budget for a Clinical Trial

As you begin to develop a budget for your Clinical Trial grant application and identify all of the relevant costs, many questions may arise. This budget cheat sheet has been designed to assist Sponsor-Investigators and research teams in developing accurate trial budgets and outlines key components which should be included for consideration.

Preparing your budget

We suggest that in the first instance, you prepare a comprehensive budget of what the trial will actually cost.

- You may then need to modify the budget for what can and/or cannot be included in a specific grant application.
- Comparing the two will allow you to calculate any shortfall amount that will need to be sourced from elsewhere
- Identify all the costs that are necessary and reasonable to complete the work described in your application. This must include the cost of support from enablers across the institute
- The best strategy is to request a reasonable amount of money to do the work, not more and not less because
    - Reviewers look for reasonable costs and will judge whether your request is justified by your aims and methods.
    - Reviewers will consider the person you've listed for each of the senior/key roles and will judge whether the figures are in sync with reviewer expectations, based on the research proposed.
    - Significant over- or under-estimating suggests you may not understand the scope of the work.

NHMRC & MRFF Direct Research Costs (DRCs)

DRCs include costs that the Research Activity's Funding Policy expressly states may be paid for with NHMRC funding. Conversely, a cost that the Research Activity's Funding Policy expressly states may not be paid for with NHMRC funding, will not be a DRC. Refer to the NHMRC DRCs Guidelines for information about costs that can or cannot be included as DRCs in NHMRC and MRFF grant applications.

Should questions arise regarding certain costs, please direct your questions as follows:

- Melbourne Children's Trial Centre: mctc@mcri.edu.au
- Clinical Research Development Office: crdo.info@mcri.edu.au
- Clinical Epidemiology & Biostatistics Unit: cebu.admin@mcri.edu.au
- MCRI Grants Team: grants@mcri.edu.au
- MCRI Insurance Team: Insurance@mcri.edu.au

For NHMRC Personnel Support Package rates

For the NHMRC Personnel Support Package rates for funding commencing in 2024, please click here. A reminder that these NHMRC rates do not fund the full cost of employing research personnel.

Budget Template

Please complete the Budget Template for the amounts you will request from NHMRC or MRFF for your Clinical Trials and Cohort Studies (CTCS) application.

The template was prepared to reflect the Sapphire budget format to make it easy for both applicants and reviewers to follow. The template does not provide macros that will automatically calculate costs.

The notes in green and links are for the applicants' consideration and should be deleted from the final document.

The below table (starting on page 2) outlines some of the common costs associated with conducting clinical trials that you might want to include in your budget, and where to seek assistance with estimating those costs.

Note: the estimated FTE provided below are based upon relatively simple trial designs, and researchers may need to estimate additional FTE for multi-site and/or complex trial designs.

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Expense	Details and MCRI Contact:
Salary	
Central Trial Coordinating Team Level	
Clinical Trial Manager Salary	A project manager experienced in designing, developing, conducting, and managing clinical trials who has a leading role in overseeing and managing the entire trial. Approx. FTE = 1.0 See Melbourne Clinical Trials Centre (MCTC): mctc@mcri.edu.au
Senior Clinical Trial Manager – Oversight Salary *(or Direct Research Cost)*	A senior clinical trials program manager working across MCRI's portfolio of investigator-led clinical trials and experienced in developing, conducting, and managing clinical trials with both local and international trial experience. Approx. FTE = 0.1 - 0.2 FTE, depending on complexity of the trial. See Melbourne Clinical Trials Centre (MCTC): mctc@mcri.edu.au
Quality Assurance (QA) & Regulatory Manager Salary *(or Direct Research Cost)*	A senior quality assurance and regulatory manager working across MCRI assisting to identify and mitigate risks in investigator-initiated clinical trials. Approx. FTE = 0.1 See Melbourne Clinical Trials Centre (MCTC): mctc@mcri.edu.au
Data Manager Salary *(or Direct Research Cost)*	An experienced clinical data manager with experience in data management and familiarity with all compliance requirements including local and international data protection regulations and data standards. Approx. FTE = 0.5 See CEBU/Data Office/Melbourne Clinical Trials Centre (MCTC): mctc@mcri.edu.au
Database Programmer/Developer Salary *(or Direct Research Cost)*	An experienced database programmer to design and build the database. Database Programmers/Developers typically design, build, and update clinical trial databases, according to standards and specifications of the protocol. They are involved from the initial drafting and building stages, through to programming of on-entry edit checks and user acceptance testing, and then through to the go-live and maintenance stages. Approx. FTE = 0.5 for Year 1-2, then 0.2 FTE for the remainder of the trial.

	See CEBU/Data Office/Melbourne Clinical Trials Centre (MCTC): mctc@mcri.edu.au
Senior Statistician – Oversight Salary *(or Direct Research Cost)*	A senior experienced clinical trial statistician to supervise the assigned trial statistician. Approx. FTE = 0.05 - 0.1 FTE for the entire trial. See Clinical Epidemiology & Biostatistics Unit (CEBU): cebu.admin@mcri.edu.au
Statistician Salary *(or Direct Research Cost)*	An experienced clinical trial statistician who will be involved from idea to publication. Approx. FTE = 0.2 for Year 1, then 0.1 FTE for the middle years and 0.4 FTE for the last year of the trial. See Clinical Epidemiology & Biostatistics Unit (CEBU): cebu.admin@mcri.edu.au
Site Team Level	
(Option 1) Study Coordinator/Research Nurse Salaries **Or refer to Option 2 below under Direct Research Costs)*	The staff based at the participating site that identify, consent, recruit, collect data, and manage queries. Approx. FTE = 0.5 See Melbourne Clinical Trials Centre (MCTC): mctc@mcri.edu.au
(Option 1) Data Entry Salary **Or refer to Option 2 below under Direct Research Costs)*	A junior project officer based at the participating site to enter site level clinical trial data and manage and respond to data queries. Approx. FTE = 0.4 See Melbourne Clinical Trials Centre (MCTC): mctc@mcri.edu.au
Direct Research Costs (DRCs)	
Central Trial Coordinating Team Level	
Institutional Sponsor Oversight– for the Trial Management Team	Costs associated with MCRI Sponsorship Committee to provide senior oversight and regular check ins with the Clinical Trial Manager and Sponsor-Investigator/CPI. See Clinical Development Research Office (CRDO): crdo.info@mcri.edu.au
Regulatory Fees, Country-Specific Set-Up Fees & Clinical Trial Registry Support Fees	Costs associated with: - Regulatory Fees (e.g. TGA Clinical Trial Notification (CTN), International regulatory body and/or data protection authority submission fees)

	- Country-Specific Set-Up Fees (e.g., fees relating to engaging with CROs or Academic Research Organisations (AROs)) - Clinical Trial Registry registration support provided by CRDO. See Melbourne Clinical Trials Centre (MCTC): mctc@mcri.edu.au
Database/System Licenses	Costs to cover the Database License for the use of the Electronic Data Capture (EDC) platform and costs for the use of the Florence eBinders™ TMF and eConsent Platform. Flat fee for Florence eBinders only: $1000 Flat fee for Florence eBinders & eConsent: $3500 Costs for use of other electronic data capture (EDC) platforms (other than REDCap) must be included as a DRC. See Melbourne Clinical Trials Centre (MCTC): mctc@mcri.edu.au
Site Monitoring of Participating Sites	Costs for annual site monitoring visits to participating sites to monitor data quality, compliance with GCP and the protocol. Includes staff and travel. Consider CRO costs if needing to engage with a third-party monitor. See Clinical Development Research Office (CRDO): crdo.info@mcri.edu.au
Quality Assurance Activities	Costs for quality assurance activities that provide MCRI Sponsor oversight of MCRI Investigator-Initiated trials. These activities include advice and support for trial team to enable compliance with regulatory requirements and internal audit. Internal audits are a requirement of GCP and the National Clinical Trials Governance Framework and will benefit the central trial coordinating team by identifying any potential issues and working with the team to implement improvements to fix them. Budget approximately $5K per year for audit and quality support. See Melbourne Clinical Trials Centre (MCTC): mctc@mcri.edu.au
Translations & Additional Study Resources	Costs associated with the professional translation of Consent Forms, all participant facing documents and study materials. Costs associated with development of additional study resources such as, trial website, educational videos to supplement informed

	consent, generation of training materials/videos, promotional material, etc. Budget approximately $5K per language for the translation of consent forms and associated documents. Budget approximately $10-15K for the production of additional study resources such as educational videos etc. See Melbourne Clinical Trials Centre (MCTC): mctc@mcri.edu.au
Research Sub-Studies & Central Labs	Costs associated with any proposed research sub-studies that may be included in the clinical trial, for example: - Biospecimen collection, handling, and storage - Analytical or central lab services - Biospecimen courier costs including shipping consumables
Consumables	Costs associated with any consumables required for the trial. e.g. consumables required to prepare laboratory kits for research sub-studies which are sent to participating sites etc
Travel	Costs associated with: - Attendance at scientific conferences/meetings for Trial Managers/Trial Coordinators/Data Managers - Accommodation for monitoring (if applicable) MCRI Assistance: mcri.travel@mcri.edu.au Lightning Travel: travelteam@1000miletravel.com.au
Trial Insurance - *International Clinical Trials only*	Clinical Trials involving International participating sites will require protocol-specific clinical trial insurance. Budget approx. $20,000 per country. See Insurance & Risk: insurance@mcri.edu.au
Pharmacy costs including Drug Distribution	Costs to purchase investigational product and/or placebo; including: - Central Pharmacy (or Central Drug Distribution) costs for ordering, storage, labelling, shipping, and dispensing trial drugs - Site Pharmacy costs for drug accountability and dispensing including drug destruction.
Medical Device including Distribution	Costs to purchase the medical devices, including: - Medical Device costs for ordering, storage, and shipping (if applicable)

Consumer Consultation	Costs for reimbursement for consumer input throughout the life of the clinical trial. MCRI advocates a remuneration of $60 per hour.
Builds for Advertising Campaigns, Social-Media Campaigns etc	Costs to generate recruitment strategies, advertising, social media campaigns (i.e. Facebook ads etc), trial websites costs etc.
Site Team Level	
Study Participating Site Start-Up Fees	Payments made to each participating study site to cover the costs of setting up the trial at that site; include costs associated with the preparation and submission, and other fees directly charged by local jurisdictions, to lodge ethics and/or competent authority applications, completion of site training and all other site initiation meeting/start-up activities. If your trial includes national centres, budget approximately $3000 - $3500 for site start-up fees for each national site participating. If your trial includes international centres, budget approximately $6000 for site start-up fees, for each international site participating.
(Option 2) Per Patient Payments to Participating Sites	Costs which may be paid to each participating site for the screening, consent and enrolment of participants, participant travel reimbursement, completion of study assessments, any interpreter fees, data collection, data entry and query management. Include payments associated with any above standard of care tests also. May need to liaise with lead site investigators to determine their site costs.
Travel	Costs associated with: - Attendance at Investigator Meetings for Trial Site Principal Investigators/Study Coordinators/Research Nurses to coincide with major scientific meetings MCRI Assistance: mcri.travel@mcri.edu.au Lightning Travel: travelteam@1000miletravel.com.au