MELBOURNE CHILDREN'S

Guidance document title: Setting up a research project budget

Document ID:

Version: 2.0

Author: Melbourne Children's Trials Centre (MCTC)

Author Signature:

Date 10 November 2016

The author is signing to confirm the technical content of this document

Line William

Reviewed and Approved by:

This signature confirms the reviewer agrees with the technical content of the document and that this document is approved for implementation at the Melbourne Children's.

Andrew Davidson - Medical Director, Melbourne Children's Trials Centre (MCTC)

Approver Signature:

Date: 10 November 2016

This document is effective from the date of the last approval signature and will be reviewed in two years.

1. PURPOSE

The purpose of this document is to outline the requirements for setting up and managing a research project budget for human research studies carried out at Melbourne Children's.

If you are unfamiliar with budgeting for research projects, you should consider registering for the budgeting workshop conducted by the Clinical Research Development Office (CRDO).

For commercially-sponsored research projects, where a proposed budget is provided prior to contract signing, it is important that the proposed budget be reviewed for completeness and accuracy of costing (i.e. to ensure that all project costs are included and that the project will be at least costneutral). Contact Melbourne Children's Trial Centre (MCTC) for advice.

2. RESPONSIBILITY AND SCOPE

This guidance applies to all Melbourne Children's employees (including visiting medical officers, visiting health professionals, contractors, consultants and volunteers of The Royal Children's Hospital, Murdoch Childrens Research Institute and Department of Paediatrics University of Melbourne) who

propose to undertake, administrate, review and/or govern human research involving Melbourne Children's patients and/or staff.

All Melbourne Children's staff planning to undertake a research project have a responsibility to ensure that good financial management practices are in place. This ensures that the researcher and the campus can meet their financial administration, accountability and reporting requirements. Careful costing of a research project should be undertaken to ensure that the budget adequately covers the direct and indirect costs of the project or that the department has adequate funds to cover a budget shortfall. In addition, payments should be tracked regularly during the project to ensure that costs are being recovered as per any agreements.

3. APPLICABILITY

The designated writer of research guidance documents and all relevant research staff.

4. PROCEDURE

A research project budget is an itemised summary of all likely income and expenses for the project duration. The project budget is also useful for monitoring (tracking) income and expenditure during the project.

A fully costed project budget* should reflect the true cost of undertaking the research, allowing any potential shortfall to be identified and steps taken to seek top up funding.

* Note that a grant application budget is unlikely to be a fully-costed project budget as a grant application budget can only cover the costs that the funding body allows (e.g. NHMRC does not allow salary on-costs and infrastructure charges). Check carefully the requirements for each funding body before applying.

4.1. Prior to research project commencement

- a) Ensure you have a copy of the research plan for the project (preferably a final protocol).
- b) Determine your source of funding
 - i. If funding is available and will be provided by a commercial sponsor*
 - Request a line item budget from the sponsor
 - Prepare a budget of your own and compare with the proposed funding negotiate your site budget to ensure that all costs are fully covered
 (maintain a record of all negotiations and agreements).
 - * For commercially-sponsored projects, it is recommended that you seek input from MCTC
 - ii. If funding is available and will be provided by a non-commercial sponsor (funding body)
 - Request a line item budget (if available)
 - Prepare a budget of your own and compare with the proposed funding determine whether all costs will be fully covered - if not, seek top-up funding from another source
 - iii. If funding has not yet been sought:

- Review the information on the <u>MCRI Grants Office</u> website (including the grants calendar) to identify appropriate grant/s and other funding opportunities.
- Prepare your project budget
- Complete Pre-Proposal Notification Form (submit to grants@mcri.edu.au)
 and then submit grant budget with grants application.

c) Use a research budget template

The following research budget templates are available to Melbourne Children's staff and can be located on the <u>Budgets</u> section of the MCRI Grants Office website

- The <u>CRDO Clinical Trials Budget Template</u> available is particularly suitable for clinical research and clinical trial projects.
- The <u>Budget Template for Grant Proposals</u> has been prepared by MCRI Finance as a planning tool and is useful for all research projects. Note that the Salaries tab provides calculations build in inflation costs over time.
- The MCRI Grants Office (grants@mcri.edu.au) can, on request, provide a budget template suitable for preparing NHMRC grant applications.

d) Seek costings

- Standard of care costs are usually covered by health service funding (e.g. Medicare) but determining standard of care can be complex given acknowledged variation in health care.
- i. Contact supporting departments:
 - Where the assistance of a Melbourne Children's department (i.e. a supporting department) is needed for your research project, provide the department contact with a copy of the project protocol or relevant sections. This will enable the supporting department to appropriately cost their services for the research budget. The involvement of the supporting departments ensures that (i) current departmental charges are being used for budgeting, (ii) the departments are aware what services are required, and (iii) there is a formal agreement for the charges of those services.
 - o Refer to the MCRI facilities and services listing
 - Check the Royal Children's Hospital website for a list of <u>RCH</u> <u>departmental contacts</u>
 - Each supporting department must complete and sign the Statement of Declaration Form. The Principal Investigator (PI) will also sign the Statement of Declaration agreeing to the estimated charges. A copy of the completed and signed form needs to be provided to RCH Research Ethics and Governance (REG) with the ethics/governance application.
 - As with any business, departmental services are subject to cost inflation; annual CPI increases may need to be incorporated into the costing of the project where the expected duration of the project covers more than two years.
- ii. Seek external quotations (where applicable)

- e) Seek approval from line manager/departmental head
 - Once the budget template has been completed, complete and loss (P&L) summary and have this printed and signed by the PI and their line manager/r departmental head.
 - If the research project is going to run at a loss, this signature indicates that the department has sufficient funds to cover any deficit.
- f) Set up a cost centre and liaise with finance department
 - i. Contact the MCRI Finance Department to allocate a new cost centre for the project. As the custodian of research at the Melbourne Children's, the MCRI manages all research funding for projects. Approval of a project will not be granted by REG until a research project-specific cost centre has been established.
- g) Submit documentation to REG:

Along with the ethics and governance application, the following information is required by REG before a research project can be approved:

- Site project budget
- Written agreement between MCRI and the project funder for clinical trial agreements (investigator-initiated and commercially-sponsored) refer to the regulatory documents process flow
- Written agreement between researcher and any supporting departments via the 'Supporting Department Declaration Form'
- The research project-specific cost centre (where funding will be paid and where money will be drawn to pay costs)

4.2. Components of a research project budget

The following section includes examples of items to consider when fully costing your research project. The list is not exhaustive and you will need to ensure that you all costs related to your project are included in your research budget.

- a) Direct costs
 - i. Personnel costs

Personnel costs include salary and on-costs. Personnel costs can be described as an hourly rate, a Full Time Equivalent (FTE) or a percentage of the staff member's time. Check with your funding source about how you can cost the personnel for your research project.

Budgeting for the research project team will differ between projects but will usually include at least a Principal Investigator (PI), Associate/Co Investigators (AI/CI) and Research Assistant/Study Coordinator /Research Nurse and/or Project Manager. Statistician and Data Manager time should also be considered.

ii. Office supplies/equipment

These must be directly related to the research project. See the <u>MCRI Equipment</u>

<u>Procurement Process Policy</u> and the MCRI <u>Equipment Purchasing Policy on</u> the MCRI

intranet. Examples of study-specific supplies or equipment may include laptops, scales, stadiometers, or sample processing and shipping supplies etc.

iii. Database and software

Research projects will require an electronic database and/or an electronic data capture tool. If unsure, contact the Clinical Epidemiology and Biostatistics Unit

(<u>CEBU</u>) to establish which database is most suitable to your project, and the associated costs (if any).

iv. Printing / photocopying / postage costs

Consider how many hard copies of key study documents will be needed. Where mailing to participants is required (e.g. surveys), determine the frequency of mailing and number of recipients as postage can be a significant cost to a project.

v. Participant assessment costs

Review the project protocol to determine which tasks / procedures will be undertaken by whom. Ensure that all tasks / procedures undertaken by those external to the research project team are costed (e.g. psychologist to perform neuropsychology assessments).

vi. Laboratory tests, imaging and other procedures

Consider standard pathology tests plus any specialist laboratory testing required and include any costs for sample processing, storage or shipping. For all other procedures seeks costs from the department responsible for undertaking the procedure, for example medical imaging for MRIs.

vii. Pharmacy fees

For those studies utilising the pharmacy department, engage early to seek feedback on the relevant sections of the protocol to ensure that the protocol is acceptable and feasible by the pharmacy department. Costs vary significantly depending on the type of study drug and how it is administered; fees may be able to be negotiated for non-commercially sponsored trials.

viii. Participant incentives and reimbursements

Participant travel reimbursement must be carefully budgeted for, especially if interstate travel may be required for participants.

ix. Meetings and travel

Funding bodies should allow costs for travel necessary to deliver the research project. Confirm by checking the funding body requirements.

For commercially-funded studies, ensure that the budget includes travel to project meetings.

x. Archiving costs

Build these in; contact the REG office at rch.ethics@rch.org.au for details.

b) Indirect Costs

i. On-costs

These are the costs that are applied on top of an employee salary and include superannuation, Workcover, and allowances for annual, long service and parental leave entitlements. At MCRI, an additional 25% should be allowed for on-costs. Check with your funding source whether on-costs can or cannot be applied; remember that salary on-costs cannot be requested in a grant application budget.

ii. Infrastructure Charge

The infrastructure charge is the fee charged by the Institute to assist in covering the costs common to all research projects (e.g. rent, electricity, research support staff). MCRI has a 20% infrastructure charge:

- Donations are exempt from the infrastructure charge.
- The infrastructure charge is not applied to certain grant funded projects (e.g. NHMRC), as the NHMRC pays an additional 20% infrastructure to MCRI for all grants received. For example, a \$200,000 grant awarded to a researcher will bring an additional \$40,000 infrastructure to MCRI for infrastructure costs.
- As a general rule, for all peer reviewed competitive grants (excluding NHMRC which
 has its own infrastructure policy) that the Institute receives, MCRI receives
 additional infrastructure funding from the government. As those income streams
 attract their own infrastructure, they are also exempt from the infrastructure
 charge.
- Any income stream that does not attract infrastructure is required to add a 20% infrastructure allowance to their budget. Examples include workshops and conferences, clinical trials and grants that are not peer reviewed.

Contact the MCRI finance department or grants office for any questions relating to indirect costs.

4.3. Justifying the budget

Consider providing the following information to a funder to justify the costs included in a budget:

- All personnel responsibilities
- All the expenses and how they were determined including any rates used to obtain the amounts
- Quotes for major equipment
- Letters of support from consultants
- Subcontract agreements and justifications

The MCRI Grants Office website includes tips on justifying your budget.

4.4. Once the research project has started

All invoicing to the funding body should be generated by MCRI Finance. A funding body/sponsor may propose issuing a Recipient Created Tax Invoice (RCTI) but MCRI Finance's preference is that it generates the invoices rather than using the RCTI process.

- a) For projects where funding is based on reaching a particular milestone (e.g. obtaining initial ethics and governance approval) and/or where payments are made on a per participant visit basis, provide MCRI Finance with regular updates on project activity.
- b) For invoices received, reconcile these against your project activity records and your budget before forwarding to MCRI Finance for payment.
- c) Track income and expenditure as listed in the project cost centre (including internal journal entries from supporting departments).
- d) Submit progress reports (where required) to the project funding body (i.e. funds received vs. funds expended).

During the course of the project, the protocol may change which may in turn require an update to the project budget. This may be negotiated with the project funder/sponsor, and a copy of the updated budget and agreement should be submitted to REG with the updated protocol. If there are any changes to the services required by the supporting departments, a new statement of declaration will need to be obtained and submitted along with this documentation.

4.5. At the end of the research project

- a) Ensure all outstanding funds due are invoiced and received (where applicable)
- b) Include a statement on project finances in the final report submitted to REG
- c) Submit final reports (where required) to the project funding body (i.e. funds received vs. funds expended)
- d) Include project-specific financial records when archiving the project

5. GLOSSARY

5.1. Financial

Income

Income or Revenue – Funds received for doing the project work

Costs – fixed, variable and mixed

Fixed Costs – Costs that do not change when there is a change in activity (e.g. rent)

Variable Costs – Costs that vary with activities undertaken (e.g. fuel, lab products)

Mixed costs – Costs that are a mixture of fixed and variable (e.g. electricity where there is a monthly service charge [fixed] then costs based on usage [variable])

Costs - direct

Direct Costs

- Direct Costs are directly attributable to the project. These include personnel salary and salary on-costs* along with items such as materials.
 - * On-costs are the costs applied on top of an employee salary, typically charged at 25% of the salary costs. These include superannuation, Workcover, and allowances for annual, long service and parental leave entitlements.

Infrastructure charge

- The infrastructure charge is the fee charged by the Institute to assist in covering the
 costs common to all research projects (e.g. rent, electricity, research support staff).
 MCRI has a 20% infrastructure charge. needs to cover to support research,
 - Donations are exempt from the infrastructure charge.
 - The infrastructure charge is not applied to certain grant funded projects (e.g. NHMRC), as the NHMRC pays an additional 20% infrastructure to MCRI for all grants received. For example, a \$200,000 grant awarded to a researcher will bring an additional \$40,000 infrastructure to MCRI for infrastructure costs.
 - As a general rule, for all peer reviewed competitive grants (excluding NHMRC which has its own infrastructure policy) that the Institute receives, MCRI receives additional infrastructure funding from the government. As those income streams attract their own infrastructure, they are also exempt from the infrastructure charge.
 - Any income stream that does not attract infrastructure is required to add a 20% infrastructure allowance to their budget. Examples include workshops and conferences, clinical trials and grants that are not peer reviewed.

Accruals, assets, liabilities and depreciation

Accruals – Accruals are used when preparing accounts, to recognise the difference between when a good or service is used, and when it is paid for. It is essentially a timing adjustment, for when to recognise income or expenses. With the exception of small businesses, all organisations are required to report using accrual-based accounting.

Assets – Assets represent what an organisation owns or is entitled to. Examples include equipment, vehicles, land and buildings, cash balances of bank accounts and investments, and accounts receivable (money owed to the organisation).

Liabilities – Liabilities represent what an organisation owes to another entity. Examples include accounts payable (money owed to another individual or organisation), annual leave and long service entitlements (owed to employees) and bank loans and overdraft facilities.

Depreciation - Depreciation is applying the accruals concept to the purchase price of an asset. It spreads the purchase price (less any residual value) of an asset over the expected life of the asset to the organisation.

GST

GST is a tax applied to goods and services of 10%. An item normally costing \$100, will have a total price of \$110 including GST. When using prices in your budgeting, you should take care to exclude the GST component of the price, as only the \$100 will be charged to your account.

Other

Recipient Created Tax Invoice (RCTI) - RCTI is an invoice created by the Funding Body issued to itself on behalf of the Research Unit. An agreement needs to exist between the institution and

the Funding Body if a RCTI is to be raised. MCRI Finance's preference is to generate invoices for research projects rather than the RCTI process.

5.2. Other

Melbourne Children's

This term is used to encompass all staff from The Royal Children's Hospital, Murdoch Childrens Research Institute and Department of Paediatrics University of Melbourne who initiate or carry out research under one or more of these institutional affiliations.

Research Project

For the purpose of this guidance, a research project is any study that requires submission to and approval from an HREC and/or research governance office. This may include (but is not limited to) observational research, clinical trials, quality assurance projects and laboratory research.

Study protocol

A document that describes the objective(s), design, methodology, statistical considerations, and organisation of a research study.

Standard of care (SOC) procedures

Standard of care is defined as how clinicians actually practice clinical care, that is, any procedures that a participant would receive in their usual course of treatment, regardless of whether they were participating in the research project. Procedures that are SOC are not usually paid for by the research project; instead they are funded by the health services funder (e.g. Medicare, the Pharmaceutical Benefits Scheme, or a patient's private health insurance).

6. ACRONYMS

CEBU: Clinical Epidemiology and Biostatistics Unit

CRDO: Clinical Research Development Office

HREC: Human Research Ethics Committee

MCTC: Melbourne Children's Trials Centre

MCRI: Murdoch Childrens Research Institute

RCH: Royal Children's Hospital

REG: RCH Research Ethics Governance

7. REFERENCES

CEBU website http://www.mcri.edu.au/research/core-facilities/cebu/

CRDO website https://www.mcri.edu.au/research/facilities-resources-and-training/clinical-research-development-office-crdo

MCTC website http://www.melbournechildrens.com/mctc/researchers/

MCRI Grants Office website https://intranet.mcri.edu.au/grants

RCH Research Ethics and Governance website http://www.rch.org.au/ethics/

RCH Research Launching Pad http://www.rch.org.au/research/researchers/

VERSION HISTORY

Prepared by: Fiona Williams

Reviewed by: Carolyn Stewart, Andrew Verberne, Marianne Ciavarella

Authorised by: Andrew Davidson

Date: November 2016

Next review date: November 2019

Change History

10/11/2016 - Final approved version - Version 2.0

26/02/2012 – Final approved version – Version 1.0