**RCH Campus Research Budget Guidelines; How to set up and manage a project budget**

The purpose of this document is to outline the requirements for setting up and managing a research project budget.

**Scope:** All campus 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 either 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, study payments should be tracked regularly during the study to ensure that costs are being recovered as per any agreements.

These guidelines will be most applicable to clinical trials (“Any research project that prospectively assigns human participants or groups to one or more health-related interventions to evaluate the effects on health outcomes”), which is usually the category that results the highest costs for the campus, however the guideline can be utilised by all researchers submitting research through Research Development & Ethics (RDE).

**Table 1:** Types of Clinical Trials by funding source

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| **Clinical Trial Type (by Funding)** | **Budget Considerations** |
| *Commercially Sponsored*  | All research costs should be covered by the commercial sponsor |
| *Collaborative Group* (often a government group, a not-for profit organisation or a disease network) | A realistic budget should be prepared (using this guideline) and much of the research costs should be incurred by the collaborative group, however supporting departments and the investigative team may be able to negotiate decreased costs  |
| *Investigator Initiated* | May be initiated by an internal investigator or an external one. Funding may be from a commercial group (at arm’s length to the study, i.e. providing funding but not sponsorship) or a grant (e.g. NHMRC). A realistic budget should be prepared (using this guideline) however supporting departments and the investigative team may be able to negotiate decreased costs and in-kind time by staff and/or departmental funding with agreement from head of department. |

 **Requirements**

1. **Prior to research project commencement**
2. Ensure you have a copy of the finalised protocol (from sponsor or written by investigator/s).
3. Determine where the funds are coming from:
	1. Commercial Sponsor;
	* Request line item budget
	* Negotiate budget ensuring you maintain an audit trial of all negotiations and agreements.
	1. Funding Body;
	* Check Grant Calendar for upcoming grants/identify appropriate grant/s
	* Complete Pre-Proposal Notification Form (submit to grants@mcri.edu.au) and then submit grant budget with grants application. *\*Note funding bodies do not cover the true research budget; your grants budget can only cover the costs the funding body allows. These requirements change with each funding body.*
4. Contact Supporting Departments:
5. Each Clinical Service department (supporting department) who may be utilised during the research project needs to be provided 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, (ii) the departments are aware what services are required, and (iii) there is a formal agreement for the charges of those services. See the ‘For Researchers’ tab of the RCH Research website for a list of departmental contacts.
6. Each supporting department will 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 RDE with the ethics/governance application.

Like 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 one financial year.

1. Complete the Budget template
2. Based on the schedule of assessments in the protocol, create a project budget and a profit/loss (P&L) statement (P&L will automatically populate from budget template). Refer to budget template for a list of potential costs to be included.
3. Ensure all procedures listed in the protocol are detailed in the budget. If the sponsor is not covering the cost for a particular procedure indentify where the funding is coming from (e.g. Medicare for a standard of care procedures)

*\*Note a grant budget does not constitute a research budget. A research budget should encompass all associated research costs, not just those that the funding body will pay for*.

1. Seek approval from line manager/departmental head
2. Once the budget template has been completed, much of the P&L spreadsheet will automatically fill but some needs to be entered manually. Once complete this must be printed and signed by the PI and their line manager or departmental head.
3. If the research project is going to run at a loss, this signature indicates that the department has sufficient funds to cover any deficit.
4. Set up a cost centre and liaise with finance department
5. Contact the Finance Department who will be administering the project funds (RCH, MCRI or UMDoP) to allocate a new cost centre for the project. See the ‘For Researchers’ tab of the RCH Research website for a list of contacts. Approval of a project will not be given by RDE until a nominated cost centre is established.
6. Submit documentation to RDE:

Along with the ethics and governance application, the following information is required by RDE before a research project will be approved;

1. Campus study budget
2. Written agreement from the researcher’s line manager/department head
3. Written agreement between RCH, UMDoP or MCRI and the project funder
4. Written agreement between researcher and any supporting departments
5. The project cost centre (defining whether MCRI or RCH), covering where external money will be paid into and where money will be drawn from to pay supporting departments
6. Details of the mechanism to be employed to regularly monitor income and expenditure, and avoid over expenditure
7. **Once the research project has started**

All invoicing to the funding body should be completed by the institution’s finance department. Invoices for research projects can be generated by the finance department of the institute administering the funds (MCRI/RCH/UMDoP) or by the Funding Body/Sponsor as a Recipient Created Tax Invoice (RCTI).

1. Upon HREC approval, request finance invoice for all start up costs (if applicable)
2. Provide finance with key milestone dates and information such as number of patients accrued and research activity undertaken.
3. Ensure invoices/journal entries are being received from supporting departments detailing all procedures undertaken, reconcile these with the budget and then forward onto finance to pay.
4. For funding bodies, submit progress reports annually or as required re: 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 can be negotiated with the project funder, and a copy of the updated budget and agreement must be submitted to the RDE with the updated/amended 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.

At least monthly review all funds being received and expended and check these against the approved research budget.

1. **At the end of the research project**
2. Prompt finance to invoice for all close out fees (if applicable)
3. Include details of financial management in project file when archiving.
4. Include a statement re: project finances in final report submitted to RDE; did the study run to budget as per the P&L.

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**APPENDIX 1: Key references, resources and templates**

Budget Template Can be found on the ‘For Researchers’ Tab of the RCH research webpage. This template includes an automatic profit and loss statement and tips when completing a budget

[Grant calendar](http://intranet.mcri.edu.au/?page_id=8616)

[Grant pre-proposal notification form](http://i-know.mcri.edu.au/%40api/deki/files/1177/%3DPre-proposal_NotificationWS.pdf)

Grants office – includes template and example budgets for grant applications (NHMRC and foundation)

[VMIA website](http://www.vmia.vic.gov.au/Risk-Management/Clinical-trials/Clinical-trials-tools-and-resources.aspx) (template Clinical Trial Research Agreements and research finance checklists)

[QLD health standard costs](http://www.health.qld.gov.au/ohmr/documents/regu/resrch_fees_v1.pdf) (examples of all trial related costs including set up and staff time)

[MCRI salary scales](http://iknow.mcri.edu.au/A/Browse_by_Department/Human_Resource/My_Pay_Scale/My_Pay_Scale)

[RCH salary scales](http://www.rch.org.au/msa/documents.cfm?doc_id=9717)

[Uni Melb salary scales](http://www.hr.unimelb.edu.au/benefits/pay/salary-scales)

[CRDO training](http://www.rch.org.au/crdo/seminars_events/Seminars_events/) – includes budgeting for research projects their workshops

[Supporting Department Statement of Declaration](http://www.rch.org.au/ethics/new_applications/)

**APPENDIX 2: Definitions**

**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. RCH/MCRI finance’s preference is to generate invoices for research projects rather than the RCTI process.

**Research Project**

A research project is any study that requires submission to and approval from the RCH HREC and/or governance office. This may include (but is not limited to) lab, translational, observation, quality assurance and randomised control trials.

**VMIA**

The Victorian Managed Insurance Authority (VMIA) is a Public Financial Corporation and is the ‘captive insurer’ for the State of Victoria. A statutory body, whose operations are governed by the [Victorian Managed Insurance Authority Act 1996](http://www.vmia.vic.gov.au/~/media/1ED8510C2F8344F19EDEF5A732E82164.pdf)*,* the VMIA reports to the Minister for Finance.

**Standard of care procedures**

Standard of care is defined as how physicians actually practice medicine, that is, any procedures that a participant would receive in their course of their treatment, regardless of their participation in the research project. These procedures are often billed to Medicare or the patient’s private hospital fund rather than the research project funder.