

GRANT BUDGETS AND TIMELINES

Grant Applications 2019

Kate Wilson, Associate Oncology Program Manager

NHMRC Clinical Trials Centre

University of Sydney

Timelines

Clinical Trials and Cohort Studies Grants

- Minimum data due in RGMS: **10 April 2019**
- *Check these dates with your administering institution*
 - E.g. First internal deadline at University of Sydney for compliance review: **15 April 2019**
 - E.g. Internal submission deadline at USYD for final compliance check and submission to NHMRC: **1 May 2019**
- Final applications due at NHMRC, lodged by administering institution Research Office **8 May 2019**

Timelines

Cancer Australia – PdCCRS Applications

- Due : **15 May 2019**
- Usually submitted via administering institution

Cancer Council NSW - NHMRC Ideas Grant / CCNSW Project Grant

Due : **22 May 2019**

- Supplementary Questions and Consumer Review Report
- Usually submitted via administering institution
- Research Grant Management Team
Email: research@nswcc.org.au

Grant Budget Requirements

- Proposed Budget
 1. Research Facilities
 2. Direct Research Costs (DRC) and Equipment
 3. Research Team – PSP Levels 1-5
 - Personal Support Package
 - Chief Investigators
 - Associate Investigators

1. Research Facilities

- Required to undertake the research proposal
- Confirm asap facility can provide services and obtain a detailed quote
- Charges included in the budget must be accurately reflected in RGMS.
- Letters from research facilities confirming their collaboration must be provided and submitted via RGMS
- Examples of facilities
 - biospecimens or data from biobanks, pathology services, Cell Bank Australia, TROG.

2. Direct Research Costs - DRC

- For each item requested you must provide:
 - the item type
 - the name/description of the item
 - the total value of the item requested for each year
 - a justification for the particular item requested
- This information must
 - be aligned with the proposed aims of the study
 - be detailed on a yearly basis
 - be fully justified (*including, in the case of equipment, why the equipment cannot be provided by the institution*).

2. Equipment – over \$10,000

- Covers equipment costing over \$10,000 essential to research
- The total equipment requested cannot exceed \$80,000
- Detail costs per annum
- Detail why equipment required and why equipment cannot be provided by institution
- Individual items of equipment costing less than \$10,000 must be requested within DRCs

3. Research Team

Funding must be spent on a cost directly incurred in relation to the Research Activity

- **Salary Support**
 - Personnel Support Packages (PSP) except for AIs
- **Support overseas grant activities and researchers**
 - Clearly demonstrate that overseas activities are critical to research
 - Cannot have international CI and draw CI salary support

3. Research Team

- The level of PSP requested in an application must match the roles and responsibilities of the position
- The percentage of the PSP requested must reflect the required time commitment.
- Applicants must fully justify all requests for PSPs.

3. Research Team – PSP levels

Personnel Support Packages for funding commencing 2020	\$ per annum
PSP1 - Technical support - non-graduate personnel	56,772
PSP2 - Junior graduate research assistant; or junior graduate nurse, midwife or allied health professional; or junior data manager/data analyst	70,890
PSP3 - Experienced graduate research assistant/junior postdoctoral research officer; or experienced graduate nurse, midwife or allied health professional; or experienced data manager/analyst	77,950
PSP4 - Experienced postdoctoral researcher (i.e., a researcher who may be considered as a named investigator on the research application and/or approaching the NHMRC CDF scheme or equivalent), or clinician without specialist qualifications	92,070
PSP5 - Senior experienced postdoctoral researcher (i.e., a researcher who would normally be considered as a named investigator on the research application and is more than 10yrs post-doctoral and/or would be expected to have applied for or held an NHMRC CDF (formerly CDA) or equivalent)	99,129

Rebuttal comment – DRC Lab

- **Direct Research Costs (DRC) - Lab**
- The molecular profiling costs are expensive, and certainly greater than is required if just measuring the features required for molecular classification
- The central pathology review fee of \$375 per case is quite high. Is this because it includes a central IHC assessment of microsatellite instability?
- Molecular profiling – cost not justified
- The budget seems reasonable. I presume other costs (such as sending viable cells express to a central lab for PDX) will be funded outside of this project grant. Could the applicant confirm?

Rebuttal comments – PSP (1)

Research Team – PSP Levels 1-5

- The clinical trials assistant does not appear to be an absolute necessity.
- The staffing costs have been carefully rationalised to fractional FTE, though the justification for PSP4 for Project Management against the PSP descriptors is not made.
- Modest budget, however, do investigators require PSP4 for statistician and project management officer?
- The budget is quite high and might require some further clarification regarding the cost of data collection and the collaborative group cost
- This is a 4-year study with plenty of input from the CIs. Site payments seem high as do central lab costs, with only limited justification for both. Isn't it likely that costs of screening tests may start decreasing?
- It was unclear what the biostatistician is doing in years 2 and 3 if the database manager is ok.

Rebuttal comments – PSP (2)

Research Team – PSP Levels 1-5

- ✓ Salary requests are reasonable.
- ✓ It's a 5 year grant, the positions are well justified in terms of FTE, as are DRCs of 1175K.
- The proposed staff costs for the project are relatively minimal, and spread out over several positions. However, the requested funding for the biostatistician is excessive at around \$50,000, given that the proposed longitudinal analyses are not overly complex and such analyses could reasonably be done by the CIs.
- The senior research assistant PSP4 (yrs 1 & 2) will process and analyse the clinical samples from Chinese patients in laboratory in China. Is this PSP being paid the Australian salary for this work, or the Chinese equivalent?

Rebuttal comments - Overall

- **General Overall Budget Comments**

- ✓ The budget is large for a radiotherapy RCT-wise
- ✓ The budget is very reasonable
- ✓ Budget seems appropriate and I can see no major flaws
- × The budget appears reasonable although I am not sure why it is expected that the NHMRC should fund an Irish arm to the study
- × The overall survival for this cancer is only 44% and in my opinion, this money would be much better directed towards finding a screening test to allow earlier diagnosis, or developing targeted therapies that would improve response rates and decrease chemotherapy related toxicity.

Rebuttal comments – DRC

Payments to collaborating hospitals

- Site payment budget (\$1500 per patient randomised x420 patients = \$ 630,000) appears high, and represents around half of total DRC budget (\$ 1.25m).
- \$4000 / patient is rather breathtaking to manage 200 patients and is a high price to pay for site co-operation.
- The Hospital Site Payments appear to total more than in the justification

Tips

- Clearly justify the requested duration of study and budget
- Ensure all PSP allocations are correct, reasonable and well justified in RGMS
- Ensure as much detail as possible is within the DRC table in RGMS
- Be defensive – cannot assume reviewer will agree on all expenditure on first review
- Rebuttals no longer performed – no case to justify or clarify your budget
- Review Assessment Snapshot from funded applications
- Aim to ultimately build templates for standard DRC items with clear justifications

Example – PET Scans

- We anticipate 15, 30, 30,30, 15 pt/yr will be recruited in 48 months over years 1-5 respectively from six sites. FDG-PET scans will be funded at \$800 per scan. The scan is integral to the study and not funded by Medicare. Sites do not have funds to support these scans and these funds are adjunct to the per patient site payment which covers other clinical trial costs at site.

Overall costs was \$96,000 - Funded

Example - site payments

- Payment \$2,500/pt recruitment for treatment & follow-up and trial-specific costs incurred by screening, scheduling trial visits, completing required assessments, completing & submitting data forms including serious adverse event reporting. Payment will cover some of costs incurred by site for trial. Most sites also receive some infrastructure & research support from other sources to subsidise these investigator initiated trials. Includes \$1000/site start up payment (10 sites).

Overall cost was \$310,000 - Funded

Example – Project Manager

- An experienced senior post graduate clinical project manager will provide clinical trial oversight and high level project management to ensure deliverables are on time and within budget. Experienced in multi-centre trial management, with post graduate qualifications & extensive trials experience. Responsibilities:
- Yr1. Development of protocol/ consent form; prepare trial documentations, prepare & review site feasibility/selection, prepare & submit lead ethics/reg submission, manage legal/contracts, prepare budget & timeline forecasting; develop monitoring plan, establish templates for reporting, management of Trial Coordinator/Data Manager.
- Yr2-5. Monitoring timelines & budgets, data quality & cleaning/resolution of queries.

Overall was \$123,000 for 5 yr = Funded at PSP Level 4

Example - Biostatistician

- A specialised post-doctorate biostatistician is required to provide statistical input, oversight and advice and perform analyses. The biostatistician will ensure data captured meets protocol requirements and the interim and final analyses are performed on time.
- Yr 1 – Will contribute to the study design and statistical section of the trial protocol and will liaise with the
- data systems development team & investigators on any modifications required to the electronic case
- research forms (eCRFs) & database design.
- Yr2-5 Will work closely with the TC/PM to review/report on data collected. Perform interim analysis.
- Yr 5 – Will perform primary endpoint analyses & final report and be closely involved in manuscript preparation for publication.

Overall was \$86,000 for 5 yr = Funded at PSP Level

Example - Laboratory

- FFPE tumour (i)Pre -treatment from 300 patients (i) disease progression 100 patients. Total 400 samples.
- Nanostring arrays @\$5,880/12 samples x 34 = \$199,920.
- NanoString nCounter Master Kit (192 assays @ \$10,750) 400 assays \$32,250 (for 3 kits).
- Equipment access costs (nCounter analysis system): \$450/12 samples x 34 = \$15300. Total = \$247,470

Ensure full details are within DRC table