Budgets
for conducting research in WA Health

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SEMINAR HANDOUT:
ADDITIONAL NOTES AND RESOURCES

CONTENTS:

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1 ADDITIONAL INFORMATION

Overview

The world of research is a constantly changing environment, greater accountability and sustainability means that organisations cannot rely on what was acceptable even 10 years ago. To be competitive, to achieve that elusive grant or sponsorship, researchers must balance the skills of ethical and scientific endeavour with project management. An increasingly important area is identifying costs, matching funding and then recovering costs. This seminar will provide strategies for developing budgets (identifying costs and funding), as well as an introduction to helpful templates and the new Research Governance Service (RGS) information system to be accessible to researchers in November 2016.

Influences on Change in Practice

In today's economic environment good clinical practice equates to sound financial governance, therefore all research projects must have rigorous financial management processes in place. It is no longer acceptable to:

- conduct a project with only ethics approval with limited information of funding source and amount
- accept sponsors budgets without question with no auditing of expenditure or payments
- perform all tests as standard of care, thereby transferring the cost to supporting departments
- pool all funding into one account without traceability
- allow Health Service Providers (HSPs) to cover deficits in funding without prior approval.

Financial management that is accurate, transparent and justifiable will ensure:

- Australia remains competitive as clinical research destination
- grant applications are competitive
- departments are reimbursed for actual time and procedures (accurate costing and invoicing)
- budgets reflect the Protocol not the sponsor's proposed budget
- financial risk reduced to organisation (funding covers costs)
- projects can continue until completion
- participants have continued access to treatments
- staff employment is maintained
- funding is restricted for purpose (correct accounts).

1.1 National influences on Research Governance

1.1.1 Research Governance Handbook

To understand the requirement for research governance and its components, investigators should refer to the National Health and Medical Research Council (NHMRC) Research Governance Handbook: Guidance for the national approach to single ethical review (December 2011) http://hrep.nhmrc.gov.au/_uploads/files/research_governance_handbook.pdf. Some extracts are provided below:

'A critical element of the new Single Ethical Review process is the need for research governance to be understood as comprising distinct elements ranging from the consideration of budgets and insurance, to the management and conduct of scientific and ethics review. **In recent years, the concept of research governance has grown from being considered an ancillary responsibility of the Human Research Ethics Committee (HREC) to one that is understood as the responsibility of the institution where the research is being conducted.**

An institution's responsibilities in the governance of research are described in the:

- NHMRC/Australian Research Council (ARC)/Universities Australia Australian Code for the Responsible Conduct of Research (2007) (**the Code**) http://www.nhmrc.gov.au/guidelines-publications/r39
- NHMRC/ARC/Australian Vice Chancellors' Committee National Statement on Ethical Conduct in Human Research (2007) (**the National Statement**) http://www.nhmrc.gov.au/guidelines/publications/e72.

The institutional consideration as to whether an individual research project is a good fit for the institution at the time it is proposed is the 'site assessment' process, sometimes known as 'research governance review'. This process takes into account the ethical review upon which the institution has chosen to rely, **institution-specific considerations such as resources, budget**, risk management, and applicable legal, regulatory, jurisdictional and other administrative requirements. The outcome of the site assessment is an institutional authorisation of a research project or a decision not to authorise a specific project.'

1.1.2 National Statement

The National Statement 5.2.7 states 'A researcher should disclose to the review body the amount and sources or potential sources of funding for the research.' This is because it is unethical to conduct a project if it is not financially viable. Therefore the investigator should consider:

- are the financial parameters of the project justified and have they been clearly documented and reviewed and approved?
- how will participants been catered for, i.e. is there adequate resources for the participants and the project to continue?
- have the participants been informed of the funding source so they can make an informed decision?

1.1.3 Good Practice Process

As part of the initiative to have more efficient research governance authorisation, the NHMRC has developed the Good Practice Process for Site Assessment and Authorisation Phases of Clinical Trial Research Governance (the Good Practice Process) 2015 https://www.nhmrc.gov.au/research/clinical-trials/development-good-practice-process-site-assessment-and-authorisation-clinica

The Good Practice Process aims to streamline the site assessment and site authorisation of clinical trials by:

- outlining a set of principles and critical success factors for site assessment and site authorisation
- detailing a set of planning and preparation activities that can made a site more responsive to commencing clinical trials
- proposing a streamlined workflow for site assessment and authorisation.

Figure 1 highlights that resourcing and budgets as a site based responsibility, should be addressed by the Sponsor, Principal Investigator (PI) and Institution streams in the feasibility and document preparation stages of the good practice process to ensure the site has the resources and capacity within a given budget.

1.1.4 Clinical Trials Ready

This NHMRC led process will recognise that clinical trial sites, including public and private hospitals and other organisations are 'ready, willing and able' to carry out high quality clinical trials in a timely, transparent and efficient manner. One of the criteria is transparent costs and overheads.

1.1.5 IHPA Standard Costs for Clinical Trials

The Independent Hospital Pricing Authority (IHPA) has developed a table of standard costs for conducting clinical trials in Australia called the Determination of standard costs associated with conducting clinical trials in Australia June 2015 https://www.ihpa.gov.au/sites/g/files/net636/f/publications/determination_of_standard_costs_associated_with_clinical_trials_in_australia.pdf . This determination does not bind jurisdictions and should be used as a guide to cost all types of clinical trials and negotiate funding with sponsors.

1.1.6 National Costing for Research

IHPA has conducted a costing study to assess the feasibility of transitioning funding for teaching, training and research (TT&R) to an activity based funding (ABF) system by 30 June 2018. For ABF purposes, the definition of research is defined as **'the public health service's contribution to maintain research capability, excluding the costs of research activities that are funded from a source other than the state or territory or provided in kind.**' It is therefore imperative that WA Health can cost the States' contribution for supporting research.

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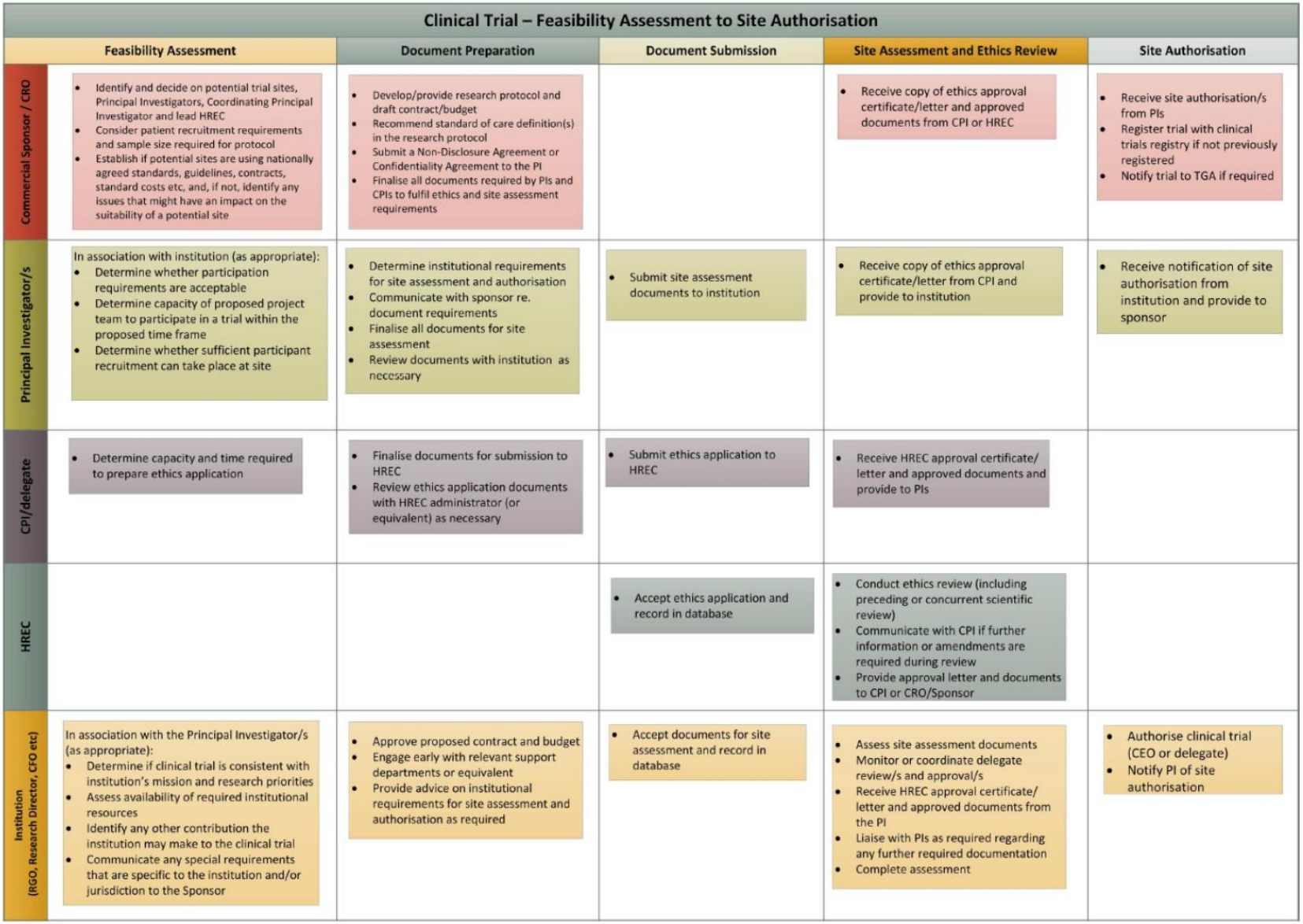

Figure 1. The high level activities, roles and responsibilities for the various components of the site assessment and authorisation process

FIGURE 1: NHMRC GOOD PRACTICE PROCESS SWIM LANE

1.2 WA Health Influences on Research Governance

1.2.1 Research Governance Framework

The Research Policy Framework specifies the research requirements that all Health Service Providers (HSPs) must comply with in order to ensure effective and consistent research activity across the WA health system.

Under this policy framework HSPs and the Department of Health must comply with all mandatory requirements related to the WA Health research governance framework including:

- OD 0411/12 WA Health Research Governance Policy and Procedures 2012 (external site)
- OD 0446/13 WA Health Research Governance and Single Ethical Review Standard Operating Procedures 2013 (external site).

The WA Health research governance framework and single ethical review of multi-centre research has affiliated ethics and governance forms and documents which support the implementation of mandatory requirements.

From December 2016, the ethics and governance application forms, including the Budget Form, which you wish to submit to a WA Health HREC or Research Governance (RG) Office in 2017, must be completed in the Research Governance Service.

2.2.2 Research Governance Service

The Research Governance Service (RGS) is a web based IT system to support the WA Health research governance framework and allow WA to participate in national initiatives, including the National Mutual Acceptance (NMA) process and National Aggregated Statistics for Clinical Trials.

It provides a collaborative workspace for investigators, project members, sponsors, sites, Research Governance Officers (RGOs) and Human Research Ethics Committees (HRECs) to govern and report on research through the life cycle of the project, from initial application to publication.

From December 2016, all new research projects requiring approval to be conducted within WA Health or accessing WA Health participants, data or tissue, must utilise the RGS.

The RGS will be implemented in 2 stages:

Stage 1 will meet the requirements of the NMA by allowing the submission and approval of research projects online. This stage encompasses the creation of users and research projects; the completion, Hospital Administrator authorisation and submission of ethics and governance applications; the review and approval by HRECs and RGOs, and site authorisation for WA Health sites involved in the research project. WA Health will work towards participating in the NMA in 2017.

Stage 1 will not involve monitoring. Monitoring forms will have to be sent to the reviewing HREC and RG Offices outside the RGS until Stage 2 is implemented.

Stage 2 will provide the ability for investigators, sponsors, sites, RGOs and HRECs to monitor and close authorised research projects. This stage encompasses the completion, submission, review and approval of monitoring forms (i.e. amendments; safety, progress and final reports; and complaints). Investigators will have the ability to add publication details to a closed or archived research project. Stage 2 will also include the migration of active and closed projects from WA Health ethics and governance office's databases to allow for WA Health-wide reporting on past and present research activity.

1.2.3 Financial Policy

Financial management of research within WA Health is also influenced by the:

- *Health Services Act 2016* (WA)
- *Financial Management Act 2006* (WA)
- *Government Financial Responsibility Act 2000*
- Treasurer's Instructions (TI)
- WA Health Financial Management Manual (FMM) – refer to the overhead policy and classifying and accounting for funds in WA Health.

A standard model for the management of clinical research funds is being developed by the Department of Health in collaboration with the HSPs and relevant stakeholders, to ensure current practices comply with relevant legislation and the TIs. Additionally, this reform process will enable the pooling of shared funds across multiple projects to support research capacity within the HSPs.

1.3 Principles to Consider when Preparing a Budget

1.3.1 Principles

A budget should be:

- **Accurate** – it should contain the best estimate of all 'research activity' costs and funding, including those that are provided in-kind
- **Transparent** – it should itemise (as much as possible) all activity and procedure items that are outlined in the Protocol, as well as the equivalent funding items itemised in the research agreements (e.g. grant, clinical trial research agreement)
- **Justifiable** – only document research activity and base quotes on actual costs not just fees. Consider only the costs to the site, not the whole project e.g. if your Human Research Ethics Committee (HREC) did not undertake the ethical review of a project then there will be no cost equated to your site.

1.3.2 Financial Management Requirements

The **OD 0411/12 WA Health Research Governance Policy and Procedures 2012** outlines the following requirements:

1. The budget must document the cost/funding of all research activity in the Protocol which is secondary to the primary purpose of providing patient care (above standard of care)[1].
2. After assessing the Protocol, the *estimated* costs for the research department must be documented in the RGS Budget Form **(Figure 6)** by the PI/delegate, including overheads (as per the FMM). The Business Manager should provide assistance with costing salaries, including on costs and specific items where required. Ethics and governance review costs should also be included.
3. Upon request from the PI/delegate, the supporting departments (Pharmacy, Pathology, Imaging etc.) must review the Protocol and document their costs in the RGS Budget Form and provide authorisation.
4. The PI/delegate must then document on the Budget Form the comparable monetary or in kind support (funding) for both the research and supporting departments costs for the project. **(Figure 7).** A total funding value will be calculated at the top of the form.
5. The PI/delegate must cover all costs with adequate funding from either:
    - external monetary funding for commercially sponsored projects
    - a combination of monetary funding and 'in kind' support for non-commercial sponsored research or institutional unfunded research.
6. With projects involving external sponsors, negotiations for funding should be based on established WA Health fee structures and justifiable costs. The RGO should provide assistance to the PI/delegate with this negotiation as required. Due to confidentiality, external sponsors must not be given access to the Budget Forms. The agreed funding and payment schedule must then be documented in the research agreement.
7. Although budgets should not include the Goods and Services Tax (GST), it should be noted that in the payment schedule of the legal agreement GST is applicable if the sponsor is an Australian entity.
8. The Site Specific Assessment (SSA) Form and Budget Form, with any supporting service agreements, should be reviewed and electronically authorised by the Heads of Research and Supporting Departments, Business Manager and Divisional Director (and Regional Director within WACHS) prior to review by the RGO. Research governance review fees will be levied for all commercially sponsored research. Final authorisation is given by the Chief Executive/delegate.

1.3.3 What will Influence the Budget

The following factors will influence the budget:

- complexity of the Protocol i.e. complex clinical trial versus simple project
- length of project as costs will be incurred across life of the project
- number of sites and supporting departments
- number of participants (people, data, samples)
- funder type i.e. commercial versus non-commercial.

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[1] According to the "Australian Hospital Patient Costing Standards v 2.0" 2011 definition, research is an activity where the primary aim is the advancement of knowledge through:

- Observation, data analysis and interpretation, or other means that are secondary to the primary purpose of providing patient care; or
- Activities associated with patient care where additional components or tasks exist (for example, the addition of control group in a cohort study).

It excludes curriculum-based research projects. Indirect or by-product research is considered as part of normal patient care and is not included in the national standard.

1.3.4 Types of Costs to Consider

The IHPA Determination of standard costs for clinical trials June 2015 can be used as a guide when considering costs that should be included in the budget. They are broken into Major Categories:

Feasibility assessment	Clinical resources
Ethics approval	Trial operation
Site-specific assessment	Participant related
Trial initiation	Amendment processing
Patient accrual	Site closeout visit
Clinical services	Record archiving
Pharmacy/Investigation drug related	Drug return/destruction
Biospecimen related	Biospecimen transfer/destruction

Some additional ones to consider include:

Feasibility: *this may not be covered by funding as it is activity that occurs prior to the commencement of the project.*

- protocol development or review
- grant application or budget preparation
- Confidentiality Agreement review
- site review
- ICT setup or development
- ethics and governance applications.

NB: Consider who will pay for this activity if the project does not progress.

Shared (Indirect): *these are non-project specific costs that can be shared to support staff salaries and wages, staff professional development and training, grants for investigator-led unfunded projects, research equipment (un-funded through the Asset Investment Program), administrative costs and utilities.*

- Research Department personnel time - investigators, clinical support, administrators, business support, statistical/economist support, interpreters
- Research Department salary based procedures e.g. vital signs, biospecimen collection, screen failures, unscheduled visits, early withdrawal
- salary based overhead
- training
- non-project specific equipment
- general administration consumables
- utilities – non-project specific ICT, telecommunications, buildings

NB: IHPA defines indirect costs as only the overhead

Project specific (Direct): *these are costs that are directly related to the project*

- all Supporting Department costs
- drugs and devices
- Research Department procedures/investigations/clinical tests if they involve more than just salaries e.g. colonic biopsy
- project specific equipment & ICT
- travel, transport
- licences
- participant payments – travel, meals, accommodation
- record/data management outside Research Department
- amendments
- project specific reporting (if involves more than research department salaries) – statistical analysis, monitoring
- archiving
- translation – policies, seminars, publications

1.4 Calculating Costs – Helpful Resources

2.4.1 Research Department

The PI/delegate should calculate the costs for the research department by considering the:

a) schedule of procedures/visits in the Protocol

b) sponsors budget spreadsheet for their schedule of procedures/visits

c) IHPA Determination of Standard Costs to consider items not addressed in a) or b)

d) Departmental costs and Medicare Benefits Schedule for non-salary based procedures http://www9.health.gov.au/mbs/search.cfm

Salary based procedural costs

Clinical trial per participant payments are often calculated based on salary based procedures that can be calculated by multiplying the project member's time (e.g. investigator, research nurse or trial coordinator) by their salary rates plus on costs. These rates can be calculated using the WA Health Research Budget Template V3.0 May 2016 (Excel 153KB) using the following steps:

1. Identify the salary rates of the Research Department staff and ensure the WA Award Rates sheet is current, update as necessary **(Figure 2)**.
2. Complete the Salary Calculator Sheet for the Research Department staff by entering in their Award Rates. Enter the on cost rate and overhead rate **(Figure 3).** The direct salary costs and on costs will flow into the Per Participant Salary Sheets **(Figure 4 & 5)**. The following should be noted:
    - on costs should be applied in accordance with FMM, the internal rate is 24%
    - overheads cover indirect costs to specialty/organisation including rent, building maintenance & utilities, support personnel & departmental charges, equipment maintenance & IT infrastructure
    - overheads should be applied in accordance with FMM, rates range from 0% (NHMRC, charities, DoH), 10%, 25% (commercial company >$10M)

- overheads should only be applied to research department salary costs (e.g. under the major category: Clinical Resources). Generally applied to participant payments as these are made up of salaries
- overheads should be calculated separately from salaries so that it can be waived if required. This is separately identified in the RGS Budget Form
- caution should be used when using IHPA's salary rates as they are fully absorbed, which includes a 33% overhead.

3. Complete either the Per Participant Salary (simple) costing template **(Figure 4)** or the Per Participant Salary (complex) costing template **(Figure 5A & B):**
    - The Simple template allows the PI/delegate to enter any salary related procedures or visits. There is a separate section for unscheduled procedures/visits. The time taken in hours for each procedure/visit is then calculated for each project member and costed. The template provides salary costs for the project for each project member (highlighted in yellow), and the cost of each procedure/visit (highlighted in green).
    - The Complex template allows the PI/delegate to enter any salary related procedures plus unscheduled procedures/visits and enter the time for each procedure/visit as well as the number of times each procedure/visit occurred. The time taken in hours for each procedure/visit is then calculated for each project member and costed. The template provides salary costs for the project for each project member (highlighted in yellow), as well as each cost for each procedure/visit (highlighted in green). **Figure 5A** shows the normal procedures and **Figure 5B** shows unscheduled procedures.

NB: Consider adjusting for future wage increases.

1.4.2 Supporting Departments

1. As part of the feasibility assessment the PI/delegate must invite all supporting departments that will be required to provide a service for the project (including normal standard of care) to review the Protocol and provide a quote on the Budget Form. All research projects that involve the use of a pharmaceutical must obtain authorisation from Pharmacy.
2. Supporting departments should review the Protocol to ascertain any research related (above standard of care) procedures that need to be provided and document their costs/authorisation in a timely manner (within 2 weeks). Additional time may be required where the project involves radiation exposure, possible dosimetry assessment and Radiological Council approval. If the procedure is deemed standard of care this should be added as a comment and the cost marked as $0.00.
3. Supporting departments should consider the Medicare Benefits Scheme (MBS) and IHPA recommendations when calculating their costs (140% MBS). Additionally, they should be open to negotiating costs or in-kind support with the PI/delegate for non-commercial projects.
4. Payments for services provided by the supporting departments are invoiced directly to the research department (based on an internal agreement) unless the supporting department has a separate external agreement with the sponsor. When supporting departments are invoicing the research department the particular project should be identified in the general ledger.

FIGURE 2: WA AWARD RATES 2015 http://www.health.wa.gov.au/awardsandagreements/

WA Award Rates used in Costing Template

Base salaries only. All relevant allowances should be costed where appropriate.

AMA: 1 October 2015	40hr/week	
Level	Annual Salary	Hourly Salary
Consultant Yr 5	$ 216,088.00	$ 103.89
Consultant Yr 8	$ 250,148.00	$ 120.26
Consultant Yr 9	$ 262,656.00	$ 126.28

Please note that these Consultant rates are base salary-rates and do not have additional allowances built in. Check with your Business Manager for rates that apply to your Department's Consultants.

ANF: 1 July 2015:	38hr/week	
Level	Annual Salary	Hourly Salary
Level 2.1	$ 86,555.00	$ 43.80
Level 2.2	$ 88,320.00	$ 44.70
Level 2.3	$ 90,123.00	$ 45.61
Level 2.4	$ 91,962.00	$ 46.54
SRN Level 1	$ 103,943.00	$ 52.60
SRN Level 2	$ 107,279.00	$ 54.29
SRN Level 3	$ 110,723.00	$ 56.03

HSU: 1 July 2015	38hr/week	
General Division Level	Annual Salary	Hourly Salary
G-3.1	$ 61,874.00	$ 31.31
G-3.2	$ 63,491.00	$ 32.13
G-3.3	$ 65,205.00	$ 33.00
G-3.4	$ 67,862.00	$ 34.34
G-4.1	$ 70,633.00	$ 35.75
G-4.2	$ 72,711.00	$ 36.80
G-4.3	$ 75,738.00	$ 38.33
G-5.1	$ 77,314.00	$ 39.13
G-5.2	$ 79,477.00	$ 40.22
G-5.3	$ 81,704.00	$ 41.35
G-5.4	$ 83,995.00	$ 42.51
G-6.1	$ 88,411.00	$ 44.74
G-6.2	$ 91,685.00	$ 46.40
G-6.3	$ 96,345.00	$ 48.76
G-7.1	$ 98,837.00	$ 50.02
G-7.2	$ 101,991.00	$ 51.61
G-7.3	$ 105,261.00	$ 53.27
G-8.1	$ 110,042.00	$ 55.69
G-8.2	$ 113,958.00	$ 57.67

Professional Division Level	Annual Salary	Hourly Salary
P-1.1	$ 68,629.00	$ 34.73
P-1.2	$ 72,711.00	$ 36.80
P-1.3	$ 77,314.00	$ 39.13
P-1.4	$ 81,704.00	$ 41.35
P-1.5	$ 88,411.00	$ 44.74
P-1.6	$ 96,345.00	$ 48.76
P-2.1	$ 98,837.00	$ 50.02
P-2.2	$ 101,991.00	$ 51.61
P-2.3	$ 105,261.00	$ 53.27
P-3.1	$ 110,042.00	$ 55.69
P-3.2	$ 113,958.00	$ 57.67
P-4.1	$ 120,302.00	$ 60.88
P-4.2	$ 124,437.00	$ 62.97
P-5.1	$ 128,972.00	$ 65.27
P-5.2	$ 136,497.00	$ 69.08
P-6.1	$ 142,324.00	$ 72.03
P-6.2	$ 148,255.00	$ 75.03
P-7	$ 156,921.00	$ 79.41
P-8	$ 162,434.00	$ 82.20
P-9	$ 168,719.00	$ 85.38

WA awards are located at the Department of Health Awards and Agreement Library
http://www.health.wa.gov.au/awardsandagreements/

FIGURE 3: SALARY RATES USED ON COSTING TEMPLATES

Salary Rates used in Costing Template

Standardised staff positions and rates 2015 - 2016:		Equivalent WA levels to IHPA levels		Salary rates in Simple & Complex Spreadsheets	Comparison against IHPA Rates	
Clinical Resources Positions	IHPA Salary Level/Grade	WA Health Salary Level/Grade	WA Health Hourly Rates (direct only)	WA Health Hourly Rates (direct & oncosts)	WA Health Hourly Rates (fully absorbed - direct, oncosts & overhead costs)	IHPA Hourly Rate (fully absorbed - direct, oncosts & overhead costs)
Investigator time – Principal investigator	AMA Yr 8-9	AMA Yr 9	$ 126.28	**$ 156.59**	$ 195.73	$ 226.11
Investigator time – sub/co- investigator	AMA Yr 5	AMA Yr 5	$ 103.89	**$ 128.82**	$ 161.03	$ 199.11
Research nurse time	Clinical Nurse Specialist Yr1-2	ANF Level 2.4	$ 46.54	**$ 57.71**	$ 72.14	$ 74.79
Clinical research coordinator (non-research nurse) time – equivalent to Clinical Trials Coordinator (CTC)	RN; Scientist Grade 3-4; Pharmacist G 3-5	HSU G-6.3	$ 48.76	**$ 60.46**	$ 75.58	$ 82.74
Clinical research coordinator (non-research nurse) time – equivalent to Clinical Trials Manager (CTM)	Clinical Nurse Consultant G3	ANF SRN Level 3	$ 56.03	**$ 69.48**	$ 86.85	$ 93.16
Clinical research coordinator (non-research nurse) time – equivalent to Clinical Trials Manager (CTM)/Clinical Trials Coordinator (CTC)	A blended CTM/CTC hourly rate	A blended CTM/CTC hourly rate	$ 52.40	**$ 64.97**	$ 81.21	$ 90.78
Interpreter services			$ -	$ -	$ -	$ 53.91

Overhead Cost Rate: 25%

Note: Should only be applied to research deparment salary costs (e.g under the IHPA major category: Clinical Resource). Financial Management Manual (FMM) for rates: Rates range from 0%, 10%, 25% depending on type of project.

Oncosts Cost Rate: 24%

WA Health Hourly Rates based on salary costs (direct + oncosts) – Refe to Financial Management Manual (FMM) for rates:
On-costs only for staff employed directly by WA Health;
On-cost internal rate: 24%
On-cost external rate: Non-medical staff 29% + Medical staff 40%

FIGURE 4: SIMPLE PER PARTICIPANT SALARY COSTING TEMPLATE

Costing Template for Clinical Resources' Salaries per Participant (Simple)

Procedures or Visits	Investigator Time (no overhead)	Research Nurse Time (no overhead)	CTC Time (no overhead)	CM Time (no overhead)	Calculated Cost based on Time (hrs) and Salary (no overhead)	Calculated Cost based on Time and Salary (including overhead)
Screening	5	5	1	0	$ 1,131.95	$ 1,414.93
Week 0	3	5	1	0	$ 818.77	$ 1,023.47
Week 2	1	3	0	0	$ 329.72	$ 412.15
Week 4	2	4	0	0	$ 544.01	$ 680.02
Week 6	1	3	0	0	$ 329.72	$ 412.15
Week 8	1	4	0	0	$ 387.43	$ 484.28
Week 10	3	8	1	0	$ 991.90	$ 1,239.88
Week 12	1	4	0	0	$ 387.43	$ 484.28
Week 14	0	6	1	0	$ 406.72	$ 508.40
SUB TOTAL	**$ 2,661.98**	**$ 2,423.80**	**$ 241.85**	**$ -**	**$ 5,327.64**	**$ 6,659.54**
Unscheduled Procedures or Visits						
Unscheduled visit	1	2	1	0	$ 332.47	$ 415.59
Early withdrawal from treatment	2	5	1	0	$ 662.18	$ 827.73
12 Week Safety - week 6	0	1	1	0	$ 118.17	$ 147.72
Week 12/ early termination	2	3	1	0	$ 546.77	$ 683.46
Unscheduled visit	1	1	1	0	$ 274.76	$ 343.45
TOTAL	**$ 3,601.51**	**$ 3,116.32**	**$ 544.16**	**$ -**	**$ 7,261.99**	**$ 9,077.48**

Note: Salary time is in hours

You can enter into the Research Governance Site Specific Assessment Budget Spreadsheet the total individual personnel salaries per participant. OR

You can enter into the Research Governance Site Specific Assessment Budget Spreadsheet the total salaries per individual procedure or visit per participant.

FIGURE 5A: COMPLEX PER PARTICIPANT SALARY COSTING TEMPLATE – Part A Normal Procedures

Costing Template for Clinical Resources' Salaries per Participant (Complex)

	Enter time in hours each person spends on each procedure					Enter number of times procedure occurs per visit (usually 1)																	
Procedures	Investigator Time (no overhead)	Research Nurse Time (no overhead)	CTC Time (no overhead)	CM Time (no overhead)	Cost per item (based on Time and Salary)	Screening	Cost	Week 0	Cost	Week 2	Cost	Week 4	Cost	Week 6	Cost	Week 8	Cost	Week 10	Cost	Week 12	Cost	Week 14	Cost	Subtotal
Informed consent	1	1	0		$ 214.30	1	$ 214.30		$ -		$ -		$ -		$ -		$ -		$ -		$ -		$ -	
Vital signs	0	1	0		$ 57.71	1	$ 57.71	1	$ 57.71	1	$ 57.71	1	$ 57.71	1	$ 57.71	1	$ 57.71	1	$ 57.71	1	$ 57.71	1	$ 57.71	
Medical history	1	1	1		$ 274.76	1	$ 274.76	1	$ 274.76		$ -		$ -		$ -		$ -		$ -		$ -		$ -	
Physical exam	1	1	0		$ 214.30	1	$ 214.30	1	$ 214.30		$ -		$ -		$ -		$ -	1	$ 214.30		$ -		$ -	
ECG	1	0	0		$ 156.59	1	$ 156.59	1	$ 156.59		$ -	1	$ 156.59		$ -		$ -	1	$ 156.59		$ -		$ -	
Adverse event monitoring	0	3	1		$ 233.59		$ -		$ -		$ -		$ -		$ -		$ -	1	$ 233.59		$ -	1	$ 233.59	
Blood draw	1	1	0		$ 214.30	1	$ 214.30	0	$ -	1	$ 214.30	1	$ 214.30	1	$ 214.30	1	$ 214.30	1	$ 214.30	1	$ 214.30		$ -	
Questionnaire	0	1	0		$ 57.71		$ -	1	$ 57.71	1	$ 57.71	1	$ 57.71	1	$ 57.71	1	$ 57.71	1	$ 57.71	1	$ 57.71	1	$ 57.71	
Data entry	0	1	0		$ 57.71		$ -	1	$ 57.71		$ -	1	$ 57.71		$ -	1	$ 57.71	1	$ 57.71	1	$ 57.71	1	$ 57.71	
Subtotal	**$ 782.94**	**$ 577.10**	**$ 120.92**	**$ -**	**$ 1,480.96**		**$ 1,131.95**		**$ 818.77**		**$ 329.72**		**$ 544.01**		**$ 329.72**		**$ 387.43**		**$ 991.90**		**$ 387.43**		**$ 406.72**	**$ 5,327.64**
Unscheduled Procedures																								
Unscheduled visit	1	2	1		$ 332.47																			
Early withdrawal from treatme	2	5	1		$ 662.18																			
12 Week Safety - week 6	0	1	1		$ 118.17																			
Week 12/ early termination	2	3	1		$ 546.77																			
Unscheduled visit	1	1	1		$ 274.76																			
Subtotal	**$ 939.52**	**$ 692.52**	**$ 302.31**	**$ -**	**$ 1,934.35**																			
TOTAL	**$ 1,722.46**	**$ 1,269.61**	**$ 423.24**	**$ -**	**$ 3,415.31**																			

Total salaries per visit																							
Investigator	5	$ 782.94	3	$ 469.76	1	$ 156.59	2	$ 313.17	1	$ 156.59	1	$ 156.59	3	$ 469.76	1	$ 156.59	0	$ -	$ 2,661.98
Research Nurse	5	$ 288.55	5	$ 288.55	3	$ 173.13	4	$ 230.84	3	$ 173.13	4	$ 230.84	8	$ 461.68	4	$ 230.84	6	$ 346.26	$ 2,423.80
CTC	1	$ 60.46	1	$ 60.46	0	$ -	0	$ -	0	$ -	0	$ -	1	$ 60.46	0	$ -	1	$ 60.46	$ 241.85
CM	0	$ -	0	$ -	0	$ -	0	$ -	0	$ -	0	$ -	0	$ -	0	$ -	0	$ -	$ -
TOTAL																			$ 5,327.64

Note: Salary time is in hours

You can enter into the Research Governance Site Specific Assessment Budget Spreadsheet the total individual personnel salaries per participant. OR

You can enter into the Research Governance Site Specific Assessment Budget Spreadsheet the total salaries per individual visit per participant.

When adding extra visits you must update these formulae

FIGURE 5B: COMPLEX PER PARTICIPANT SALARY COSTING TEMPLATE – Part B Unscheduled Procedures

Costing Template for Clinical Resources' Salaries per Participant (Complex)

	Enter time in hours each person spends on each procedure					Enter number of times procedure occurs per visit (usually 1)											
Procedures	Investigator Time (no overhead)	Research Nurse Time (no overhead)	CTC Time (no overhead)	CM Time (no overhead)	Cost per item (based on Time and Salary)	Unscheduled visit	Cost	Early withdrawal from treatment	Cost	12 Week Safety - week 6	Cost	Week 12/ early termination	Cost	Unscheduled visit	Cost	Total	Cost based on Time and Salary (including overhead)
Informed consent	1	1	0		$ 214.30		$ -		$ -		$ -		$ -		$ -	$ 214.30	$ 267.87
Vital signs	0	1	0		$ 57.71		$ -		$ -		$ -		$ -		$ -	$ 519.39	$ 649.23
Medical history	1	1	1		$ 274.76		$ -		$ -		$ -		$ -		$ -	$ 549.52	$ 686.90
Physical exam	1	1	0		$ 214.30		$ -		$ -		$ -		$ -		$ -	$ 642.89	$ 803.61
ECG	1	0	0		$ 156.59		$ -		$ -		$ -		$ -		$ -	$ 626.35	$ 782.94
Adverse event monitoring	0	3	1		$ 233.59		$ -		$ -		$ -		$ -		$ -	$ 467.18	$ 583.98
Blood draw	1	1	0		$ 214.30		$ -		$ -		$ -		$ -		$ -	$ 1,500.08	$ 1,875.10
Questionnaire	0	1	0		$ 57.71		$ -		$ -		$ -		$ -		$ -	$ 461.68	$ 577.10
Data entry	0	1	0		$ 57.71		$ -		$ -		$ -		$ -		$ -	$ 346.26	$ 432.82
Subtotal	**$ 782.94**	**$ 577.10**	**$ 120.92**	**$ -**	**$ 1,480.96**		**$ -**		**$ -**		**$ -**		**$ -**		**$ -**	**$ 5,327.64**	**$ 6,659.54**
Unscheduled Procedures																	
Unscheduled visit	1	2	1		$ 332.47	1	$ 332.47		$ -		$ -		$ -		$ -	$ 332.47	$ 415.59
Early withdrawal from treatm	2	5	1		$ 662.18		$ -	1	$ 662.18		$ -		$ -		$ -	$ 662.18	$ 827.73
12 Week Safety - week 6	0	1	1		$ 118.17		$ -		$ -	1	$ 118.17		$ -		$ -	$ 118.17	$ 147.72
Week 12/ early termination	2	3	1		$ 546.77		$ -		$ -		$ -	1	$ 546.77		$ -	$ 546.77	$ 683.46
Unscheduled visit	1	1	1		$ 274.76		$ -		$ -		$ -		$ -	1	$ 274.76	$ 274.76	$ 343.45
Subtotal	**$ 939.52**	**$ 692.52**	**$ 302.31**	**$ -**	**$ 1,934.35**		**$ 332.47**		**$ 662.18**		**$ 118.17**		**$ 546.77**		**$ 274.76**	**$ 1,934.35**	**$ 2,417.94**
TOTAL	**$ 1,722.46**	**$ 1,269.61**	**$ 423.24**	**$ -**	**$ 3,415.31**											**$ 7,261.99**	**$ 9,077.48**

Total salaries per visit													
Investigator	1	$ 156.59	2	$ 313.17	0	$ -	2	$ 313.17	1	$ 156.59	$ 3,601.51	$ 4,501.88
Research Nurse	2	$ 115.42	5	$ 288.55	1	$ 57.71	3	$ 173.13	1	$ 57.71	$ 3,116.32	$ 3,895.40
CTC	1	$ 60.46	1	$ 60.46	1	$ 60.46	1	$ 60.46	1	$ 60.46	$ 544.16	$ 680.20
CM	0	$ -	0	$ -	0	$ -	0	$ -	0	$ -	$ -	$ -
TOTAL											**$ 7,261.99**	**$ 9,077.48**

Note: Salary time is in hours

You can enter into the Research Governance Site Specific Assessment Budget Spreadsheet the total individual personnel salaries per participant. OR

You can enter into the Research Governance Site Specific Assessment Budget Spreadsheet the total salaries per individual visit per participant.

When adding extra visits you must update these formulae

1.5 Funding considerations

1.5.1 Types of Funder and Funding

Funders may be:

- Commercial Company – Industry / Contract Research Organisation
- Collaborative Research Group
- Government - Commonwealth
- Government - State (WA)
- Government - State/Territory (Non-WA)
- Not for Profit
- University
- Other e.g. self-funded

Funding may be:

- Grant
- Sponsor
- Fee for service
- In-kind support

1.5.2 Payment type

Payments may be up-front versus recoup basis; adhoc versus regular payments; or bundled versus itemised.

1.5.3 Cost Recovery

For commercial projects there should be full cost recovery. In the cases of non-commercial projects the investigator will have to negotiate with the site and supporting departments if they can provide in-kind support or provide operational funding.

1.5.4 Negotiating with the funder

If possible negotiate with the funder for additional funding. Transparency of costs and knowing your protocol will facilitate this process. Be prepared to give and take within reason and consider renegotiation with your supporting departments.

1.5.5 Funding Agreements

All external funding should have an agreement and it should reflect the budget. Ensure it contains a payment schedule and details whether payments will be bundled or itemised. Consider whether supporting departments will be payed separately and whether invoicing will be direct or there will be a Recipient Created Tax Invoice. Also consider GST.

NB: Don't forget to invoice!

1.6 Entering the Costs and Funding into the RGS

1.6.1 The process to complete and authorise the SSA and Budget forms

In the RGS the Budget Form is separate from the SSA Form. Authorisation within the Budget Form is related to the costs and funding of the project. Authorisation within the SSA Form is related to the whole project (including costs & funding).

The following roles have responsibilities for completing and authorising the costs and funding associated within the project in either the SSA Form or Budget Form:

1. The PI/delegate should:
    - add the proposed number of participants for the site and expected project timeframe for the site in the Budget Form 'Department Selection'
    - add the research department, third party agencies (e.g. radiology services outside WA Health) and supporting departments to the Budget Form 'Department Selection' and invite Heads of Supporting Departments (HoSDs) to provide a quote
    - indicate to the supporting departments the types of 'Service/Support Items' that should be provided by them. This is done be selecting them in under that department in the Budget Form 'Site Project Budget'. This is not mandatory and may be left to the HoSDs to select
    - complete the costs and funding for any third party agencies based on the Protocol and authorise them
    - complete the costs for the research department based on the Protocol (refer to section 1.4.1) and enter the associated funding
    - complete the Budget Form 'Site Project Funding/Support' for the supporting departments once HoSDs have entered and authorised their costs
    - once all the funding is entered for the research department, invite your Head of Research Department (HoRD) to authorise the budget for the research department
    - authorise the Budget Form 'Site Project Funding/Support' once completed
    - sign the SSA Form (PI only, not the delegate) once the Budget Form is authorised and the SSA Form has been marked complete
    - Invite the Business Manager, Divisional Director and if applicable Regional Director (WACHS) to sign the SSA Form
    - authorise the SSA Form once all signatures are obtained and then submit the both the SSA and Budget forms together to the RG Office.
2. The HoSDs should:
    - accept the invitation to the project, complete the costs for their supporting department based on the Protocol and authorise them
    - add a comment to the Budget Form if they decide to decline providing a service
    - complete the 'Site Project Funding/Support' for their supporting departments if they are prepared to provide in-kind support to cover their costs.

3. The HoRD should:
    - accept the invitation to the project, review the research department costs and funding project and provide authorisation for the research department in the Budget Form 'Site Project Budget'.
4. The Business Manager, Divisional Director and if applicable Regional Director (WACHS) should:
    - accept the invitation to the project, review the SSA Form and Budget Form and provide authorisation on the SSA Form.

1.6.2 Calculating Research Department costs & funding in the RGS Budget Form

1. The salary based Service/Support item costs should be entered into the Budget Form 'Site Project Budget' either as the total salary per project member (**Figure 6**) or broken down as salaries per procedure/visit for one participant. The amount should then be multiplied by the number of participants (Quantity) to calculate the Total Cost.
2. The PI/delegate should then enter any non-salary based costs that will be incurred by the research department. They should:
    - select the relevant Service/Support item
    - enter a cost description if this item does not match what it is called in the department or on the funding agreement
    - enter the cost per item
    - enter the quantity of the item (i.e. the. number of tests x participants x project timeframe in years) to arrive at a total cost
    - select whether the cost is Project Specific (e.g. procedures) or Shared (e.g. salaries)
    - select whether overhead charges apply to a service/support item. Overheads should only be applied to research department salary costs (e.g. under the major category: Clinical Resources). Generally applied to participant payments as these are made up of salaries.
3. If the PI/delegate uses the IHPA cost schedule for fixed costs, the PI/delegate should be mindful that costs are often:
    - bundled i.e. they include research department and supporting department costs combined for a specific item (e.g. Feasibility determination – study site visit). Therefore these costs should be unbundled or not replicated in both departments
    - fully absorbed rates i.e. they include 33% overhead. Therefore the overhead should be removed (divide the amount by 1.33), and then the correct FMM overhead applied.
4. In clinical trials some costs may be fixed (e.g. archiving) or pass through (e.g. participant travel). Fixed costs are easier to identify and match funding but as pass through costs may only occur on an adhoc basis they may be harder to estimate. For pass through costs ensure the potential number of instances you have estimated is the same for costs and funding. There may also be a capped amount to consider.
5. Once the entire research department **(Figure 6)** and supporting department's costs are entered in the Budget Form 'Site Project Budget' (refer to section 1.6.1), the PI/delegate should complete the funding (monetary and in-kind) in the Budget Form

'Site Project Funding / Support' to align with the cost items **(Figure 7)**. Some funding amounts may cover several cost items.

6. A comparison of Total Actual Costs versus Total Funding is provided at the top of the Budget Form with either a Shortfall or Surplus calculated. If the budget is in deficit then an explanation must be provided for how the costs will be met in the General Comments section.
7. Once the budget is completed, the PI/delegate will invite the HoRD to authorise the budget for the research department.
8. The PI/delegate will then invite the Business Manager, Divisional Director and if applicable Regional Director (WACHS) to review the Budget and SSA forms and sign the SSA Form.

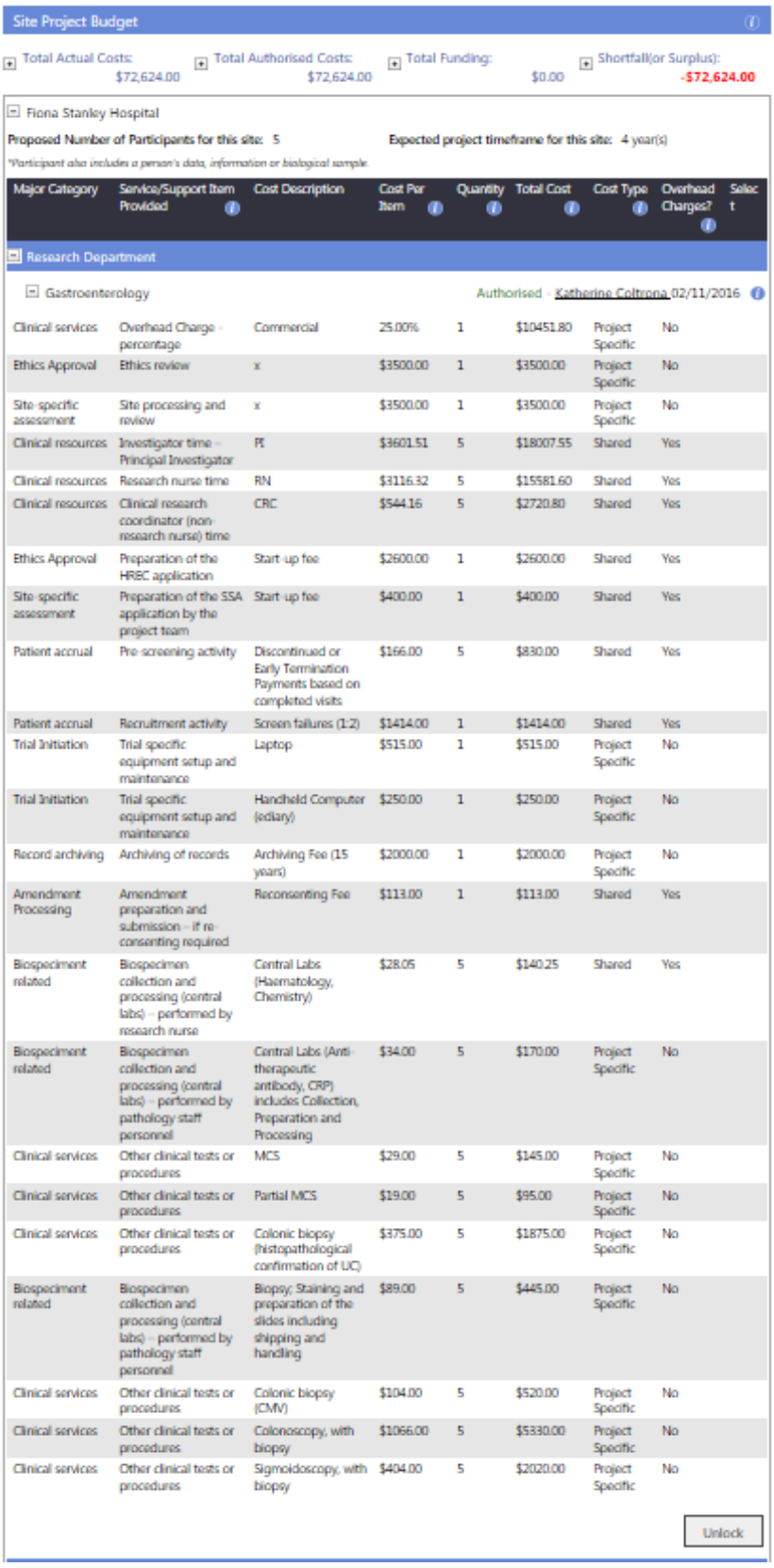
NB: If you calculate costs in the feasibility stage, these costs can be used to formulate a Grant Application.

1.6.3 Documenting costs & funding in the Ethics Application Form

The costs and funding entered into the Ethics Application Form are *the total costs and funding for all sites involved with the project that fall within that ethics application*. That is, all sites that the reviewing HREC will be giving ethical approval for. It does not include sites that fall under the review of another external HREC.

As not all site authorisations will be completed when submitting an ethics application, the total project costs and funding may be an estimate. The HREC is more interested in the ethical implications related to whether the project has sufficient funding to maintain its activity for the life of the project.

FIGURE 6: COMPLETED RGS RESEARCH DEPARTMENT 'SITE PROJECT BUDGET' (COSTS)



Site Project Budget

Total Actual Costs: $72,624.00 | Total Authorised Costs: $72,624.00 | Total Funding: $0.00 | Shortfall(or Surplus): -$72,624.00

Fiona Stanley Hospital

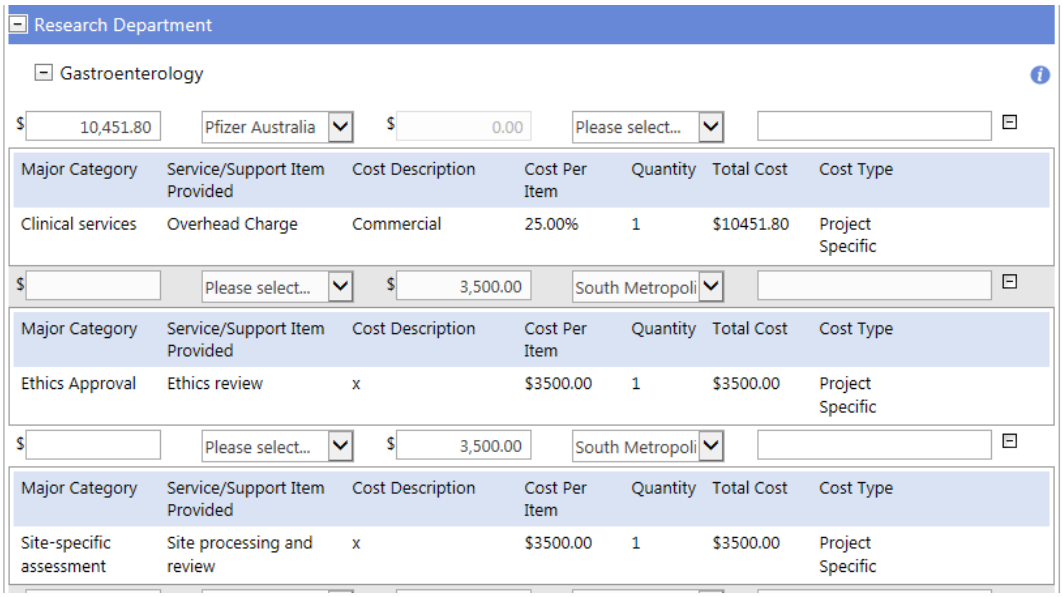
Proposed Number of Participants for this site: 5 Expected project timeframe for this site: 4 year(s)

*Participant also includes a person's data, information or biological sample.

Major Category	Service/Support Item Provided	Cost Description	Cost Per Item	Quantity	Total Cost	Cost Type	Overhead Charges?	Select
Research Department								
Gastroenterology					Authorised - Katherine Coltrona 02/11/2016			
Clinical services	Overhead Charge - percentage	Commercial	25.00%	1	$10451.80	Project Specific	No	
Ethics Approval	Ethics review	x	$3500.00	1	$3500.00	Project Specific	No	
Site-specific assessment	Site processing and review	x	$3500.00	1	$3500.00	Project Specific	No	
Clinical resources	Investigator time - Principal Investigator	PI	$3601.51	5	$18007.55	Shared	Yes	
Clinical resources	Research nurse time	RN	$3116.32	5	$15581.60	Shared	Yes	
Clinical resources	Clinical research coordinator (non-research nurse) time	CRC	$544.16	5	$2720.80	Shared	Yes	
Ethics Approval	Preparation of the HREC application	Start-up fee	$2600.00	1	$2600.00	Shared	Yes	
Site-specific assessment	Preparation of the SSA application by the project team	Start-up fee	$400.00	1	$400.00	Shared	Yes	
Patient accrual	Pre-screening activity	Discontinued or Early Termination Payments based on completed visits	$166.00	5	$830.00	Shared	Yes	
Patient accrual	Recruitment activity	Screen failures (1:2)	$1414.00	1	$1414.00	Shared	Yes	
Trial Initiation	Trial specific equipment setup and maintenance	Laptop	$515.00	1	$515.00	Project Specific	No	
Trial Initiation	Trial specific equipment setup and maintenance	Handheld Computer (ediary)	$250.00	1	$250.00	Project Specific	No	
Record archiving	Archiving of records	Archiving Fee (15 years)	$2000.00	1	$2000.00	Project Specific	No	
Amendment Processing	Amendment preparation and submission - if re-consenting required	Reconsenting Fee	$113.00	1	$113.00	Shared	Yes	
Biospecimen related	Biospecimen collection and processing (central labs) - performed by research nurse	Central Labs (Haematology, Chemistry)	$28.05	5	$140.25	Shared	Yes	
Biospecimen related	Biospecimen collection and processing (central labs) - performed by pathology staff personnel	Central Labs (Anti-therapeutic antibody, CRP) includes Collection, Preparation and Processing	$34.00	5	$170.00	Project Specific	No	
Clinical services	Other clinical tests or procedures	MCS	$29.00	5	$145.00	Project Specific	No	
Clinical services	Other clinical tests or procedures	Partial MCS	$19.00	5	$95.00	Project Specific	No	
Clinical services	Other clinical tests or procedures	Colonic biopsy (histopathological confirmation of UC)	$375.00	5	$1875.00	Project Specific	No	
Biospecimen related	Biospecimen collection and processing (central labs) - performed by pathology staff personnel	Biopsy; Staining and preparation of the slides including shipping and handling	$89.00	5	$445.00	Project Specific	No	
Clinical services	Other clinical tests or procedures	Colonic biopsy (CMV)	$104.00	5	$520.00	Project Specific	No	
Clinical services	Other clinical tests or procedures	Colonoscopy, with biopsy	$1066.00	5	$5330.00	Project Specific	No	
Clinical services	Other clinical tests or procedures	Sigmoidoscopy, with biopsy	$404.00	5	$2020.00	Project Specific	No	

Unlock

FIGURE 7: COMPLETED RGS RESEARCH DEPARTMENT SITE PROJECT FUNDING / SUPPORT



Research Department

Gastroenterology

$			$		
10,451.80	Pfizer Australia		0.00	Please select...	

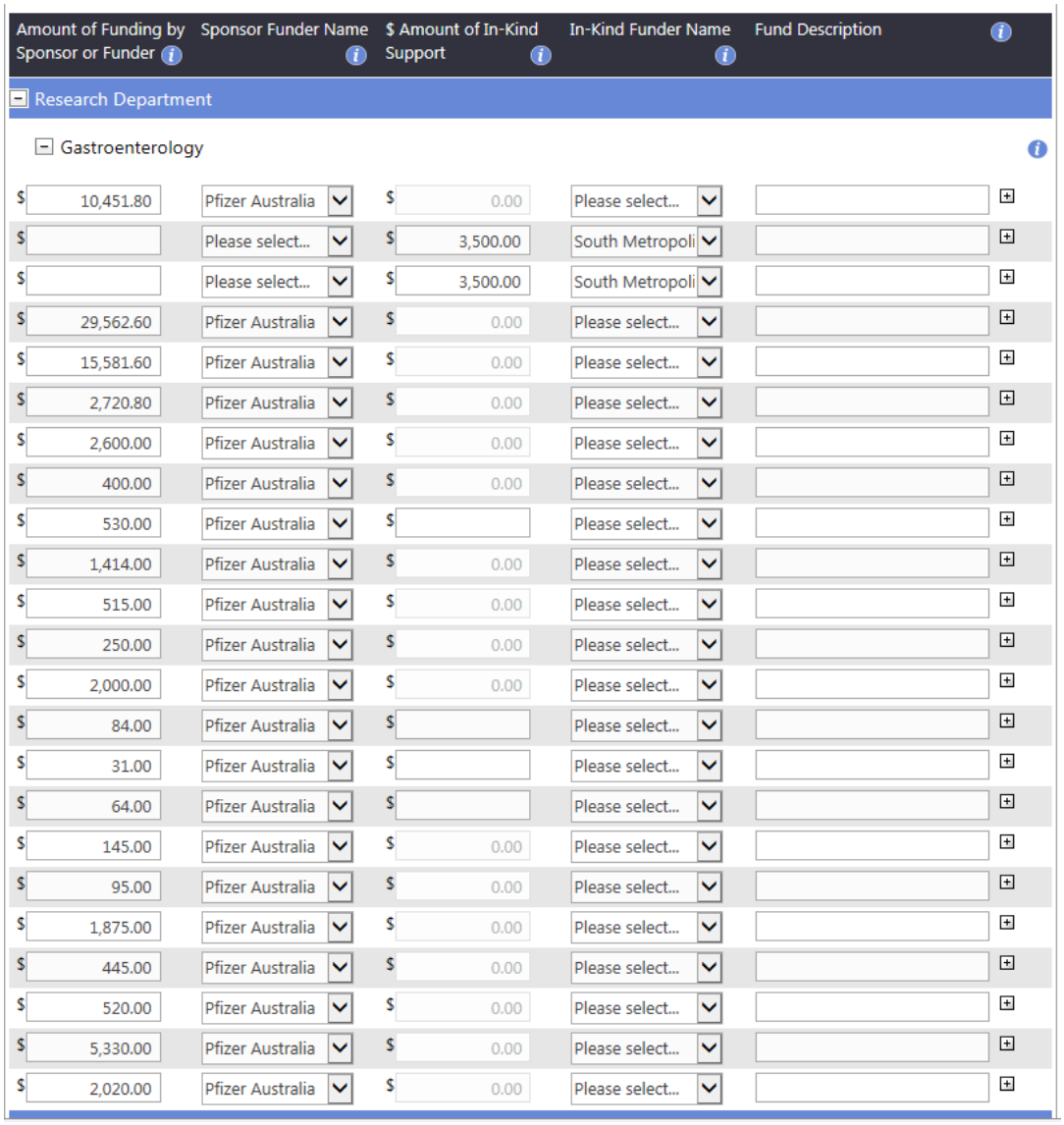
Major Category	Service/Support Item Provided	Cost Description	Cost Per Item	Quantity	Total Cost	Cost Type
Clinical services	Overhead Charge	Commercial	25.00%	1	$10451.80	Project Specific

$			$		
	Please select...		3,500.00	South Metropoli	

Major Category	Service/Support Item Provided	Cost Description	Cost Per Item	Quantity	Total Cost	Cost Type
Ethics Approval	Ethics review	x	$3500.00	1	$3500.00	Project Specific

$			$		
	Please select...		3,500.00	South Metropoli	

Major Category	Service/Support Item Provided	Cost Description	Cost Per Item	Quantity	Total Cost	Cost Type
Site-specific assessment	Site processing and review	x	$3500.00	1	$3500.00	Project Specific



Amount of Funding by Sponsor or Funder	Sponsor Funder Name	$ Amount of In-Kind Support	In-Kind Funder Name	Fund Description
Research Department				
Gastroenterology				
$ 10,451.80	Pfizer Australia	$ 0.00	Please select...	
$	Please select...	$ 3,500.00	South Metropoli	
$	Please select...	$ 3,500.00	South Metropoli	
$ 29,562.60	Pfizer Australia	$ 0.00	Please select...	
$ 15,581.60	Pfizer Australia	$ 0.00	Please select...	
$ 2,720.80	Pfizer Australia	$ 0.00	Please select...	
$ 2,600.00	Pfizer Australia	$ 0.00	Please select...	
$ 400.00	Pfizer Australia	$ 0.00	Please select...	
$ 530.00	Pfizer Australia	$	Please select...	
$ 1,414.00	Pfizer Australia	$ 0.00	Please select...	
$ 515.00	Pfizer Australia	$ 0.00	Please select...	
$ 250.00	Pfizer Australia	$ 0.00	Please select...	
$ 2,000.00	Pfizer Australia	$ 0.00	Please select...	
$ 84.00	Pfizer Australia	$	Please select...	
$ 31.00	Pfizer Australia	$	Please select...	
$ 64.00	Pfizer Australia	$	Please select...	
$ 145.00	Pfizer Australia	$ 0.00	Please select...	
$ 95.00	Pfizer Australia	$ 0.00	Please select...	
$ 1,875.00	Pfizer Australia	$ 0.00	Please select...	
$ 445.00	Pfizer Australia	$ 0.00	Please select...	
$ 520.00	Pfizer Australia	$ 0.00	Please select...	
$ 5,330.00	Pfizer Australia	$ 0.00	Please select...	
$ 2,020.00	Pfizer Australia	$ 0.00	Please select...	

1.7 Accountancy

1.7.1 Track expenditure

Investigators should consider maintaining a debit/credit spreadsheet to track actual budget expenditure, this:

- allows financial monitoring of project to ensure viability
- aids future budget planning
- monitors invoicing and sponsor payments, thereby ensuring all items in the agreement are correctly invoiced
- assists renegotiation of the budget if you are providing unpaid services not in original Protocol.

If an Amendment changes the budget, the investigator should update the Budget Form and resubmit it to the RGO with an updated agreement.

1.7.2 What accounts to use for external funds

Currently within WA Health the following accounts can be used for external research funds:

1. Externally Restricted Cost Centre (ERCC):
    - Must be external funds.
    - Restricted cash can roll over financial years.
    - Must have a documented special purpose (e.g. CTRA) – no blended funds and document use of residual funds.
    - Cannot go into deficit, therefore it cannot operate on a recoup basis if there are insufficient funds in the CC. NOTE: most clinical trials operate on recoup.
    - Set up Requires:
        - Executed Agreement
        - ERCC form – 905-1
2. Transitional Externally Restricted Cost Centre (XCC)
    - This allows for pooling of previous SPA money until it is spent.

NB: Current WA Health management of clinical research funds is under review to allow for the pooling of shared costs across projects.

1.7.3 What accounts to use for internal funds

Internal WA Health funds (e.g. Department of Health grants) cannot be managed in ERCCs. Investigators must use an operating account. This does not allow for the roll of funds over fiscal years, therefore requires forward projection outlining fiscal year expenditure. These accounts can go into a deficit but must be managed.

1.8 Resources

1.8.1 Resource staff

- Dedicated administration and finance staff.
- Business Managers can provide information on salaries, on costs, overheads, opening accounts, transferring funds across Health Services.

1.8.2 ICT

- RGS http://ww2.health.wa.gov.au/Health-for/Researchers-and-educators/Research-governance
- Project and financial management software.

1.8.3 Templates

- WA Health Research Budget Template http://ww2.health.wa.gov.au/Articles/N_R/Research-governance-forms

1.8.4 Documents

- Independent Hospital Pricing Authority (IHPA) Determination of standard costs associated with conducting clinical trials in Australia June 2015 https://www.ihpa.gov.au/sites/g/files/net636/f/publications/determination_of_standard_costs_associated_with_clinical_trials_in_australia.pdf
- Published departmental & organisation fee schedules.

1.8.5 Websites

- Medicare Benefits Schedule http://www9.health.gov.au/mbs/search.cfm
- Awards http://www.health.wa.gov.au/AwardsAndAgreements/
- Department of Health http://ww2.health.wa.gov.au/Health-for/Researchers-and-educators/Research-governance

  http://ww2.health.wa.gov.au/Articles/A_E/Clinical-trials-and-research-governance-education

1.8.6 Policy Advice

Katherine Coltrona, Senior Policy Officer
Research Development Unit, Office of the Chief Medical Officer, Clinical Services and Research
Department of Health
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