



Government of **Western Australia**
Department of **Health**

Site Specific Assessment (SSA) Budget Workshop

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Program



Principles



SSA budget



Example

Change in Practice



National



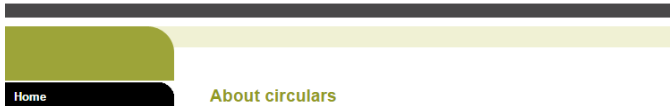
- Research Governance Handbook
- National Statement
- Good Practice Process
- Clinical Trials Ready



- Clinical trials standard costs
- NEP for Research

WA Health

Operational Directives and Information Circulars



- Research Governance Policy and Procedures 2012
- Research Governance and Single Ethical Review Standard Operating Procedures 2013

A screenshot of the Government of Western Australia Department of Health website. The header includes the government logo and the text 'Government of Western Australia Department of Health'. Below the header is a navigation menu with links for 'Form Search', 'Finance Home', 'Branches', 'Processes', 'Forms', 'Policies & Procedures', 'Manuals', and 'Chart Of Accounts'. The main content area is titled 'Health Corporate Network' with the tagline 'Making it Easier for WA Health to do Business'. A search box is visible. Below the search box is a 'Main Menu' section with links for 'HCN Home', 'Business Systems', 'Finance', 'Human Resources', 'Supply', and 'Jobs in Health'. The 'Health Accounting Manual' link is highlighted, and its description is shown: 'The Health Accounting Manual is the document to be used as the principal reference point for financial management and accounting principles, policies and procedures to be adopted by all WA Health Entities. The Health Accounting Manual is representative of current business practises and encompasses issues such as accrual accounting, output based management, accrual budgeting and the usage of a shared service environment (Health Corporate Network). It is being developed to ensure a comprehensive financial and accounting manual is available for WA Health Entities.'

- *Financial Management Act 2006 (WA)*
- *Hospitals and Health Services Act 1927 (WA)*
- Treasurer's Instructions
- Health Accounting Manual (HAM)

All research projects require a budget

Research Governance Service

RGS

Department of Health
GOVERNMENT OF WESTERN AUSTRALIA

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Research Governance Service

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Sign Up

Home

Welcome to the Research Governance Service (RGS)

RGS is an information technology system which supports the research governance framework for conducting WA Health human research projects.

The RGS is a centralised system for investigators, research group members and sponsors to complete, submit, manage and track their ethics and governance documentation through the lifecycle of their human research project. This includes approval/authorisation, monitoring and publication.

In addition, the service provides for Ethics, Research Governance and Hospital Administrators, Human Research Ethics Committees (and Subcommittees) to administer and report on all human research conducted within WA Health or accessing WA Health participants, their tissue or data.

Sign into RGS

Not an RGS User? Sign up

Announcements

There are no items to show in this view.

Events

There are no items to show in this view.

PROJECT | Investigating the magical properties of dragon scale and its use in defense against the dark arts

PRN: PRN0000000004 Project status: Active Ethics approval status: Pending
 Project type: Research Short title: Dragon scale use for defense against the dark arts
 Protocol number: PVS3 Acronym: CPI: Minerva McGonagall
 External HREC ref: Lead HREC:

Timeline	Summary	Project Details	Members	Sites
Declarations	Forms & Documents	Letters	Comments	Administration
Publications	Reports	History		

- July 2016
- Separate budget spreadsheet
- IHPA categories
- Costing: electronic quotes & authorisation
- Funding: amount, name, type

Technical Assistance:
 Phone: 1300 1700 89
 Hours: 7:30am to 5:00pm
 Email: HN.ServiceDesk@health.wa.gov.au

Contacts:
 WA Health HRECs
 Specialist HRECs External to WA Health
 WA Health RGOs

Budget elements

- **ACCURATE**
(best estimate)
- **TRANSPARENT**
(itemised to reflect protocol)
- **JUSTIFIABLE**
(ability to justify costs)



CORRECT: Costs Funding Accounts

Influences



Feasibility

Document Preparation

Submission and Review

Approval and Authorisation

Recruitment and Monitoring

Project Closure

Publications

Archiving

IHPA Standard Costs for Clinical Trials

Major Categories

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

IHPA Service and Support Values					
Reference Number	Major category	Item	Guidance Text	Recommended Standard Cost	Comments to guide use of the standard cost
Sub-List 1 – SITE AUTHORISATION					
L1.1	Feasibility Assessment	Preliminary assessment	The activities associated with the exchange of the required reciprocal confidentiality agreements and preliminary review of a clinical trial protocol by the potential site PI (and/or delegates). May also include initial discussions (by telephone or site visit) with the trial sponsor and/or representative.	\$60.38 per potential clinical trial	Based on the assumption that the PI and CTMC are the only two involved in a preliminary assessment and that the hourly rate (fully absorbed) of the PI is \$226.11/hour (as defined in item 2.6.1) and \$90.78/hour for CTMC (as defined in item 2.6.3). <ul style="list-style-type: none"> • Standard cost is calculated using the 25th percentile of the gathered data. • Potential outliers (i.e. data is suggestive although a large enough sample not available/gathered due to scope of project) were the paediatric clinical trials and Phase 1 clinical trials where the protocol is typically more detailed and requires more consideration (i.e. extra time) and hence the 25th percentile may be too low for these types of trials. • Although the costs are incurred by the clinical trial site the costs were not included in any clinical trial budget, as the activities occur before site selection, and are considered by Sponsors to be part of the tendering process for site selection.
L1.2		Protocol review	The activities associated with the heads (or nominees) within the potential clinical trial host unit (e.g. oncology, respiratory, etc.) in addition to the supporting departments (e.g. pharmacy, pathology, radiology, radiation therapy, other clinical specialties, clinical trials office/governance office, etc.) reviewing the clinical trial protocol for scientific merit and local interests/feasibility. The process may involve review by individuals or by a panel drawn from the activities associated with determining the feasibility and desirability of conducting the trial at a site (culminating with the completion of the feasibility assessment questionnaire) covering the assessment of whether trial is consistent with institution's mission, research priorities and risk management	\$407.67 per potential clinical trial	Based on the assumption that the PI and CTMC are the only two involved in protocol review and that the hourly rate (fully absorbed) of the PI is \$226.11/hour (as defined in item 2.6.1) and \$90.78/hour for CTMC (as defined in item 2.6.3). <ul style="list-style-type: none"> • Standard cost is calculated using the median of the gathered data. • Although the costs are incurred by the clinical trial site the costs were not included in any clinical trial budget, as the activities occur before site selection, and are considered by Sponsors to be part of the tendering process for site selection.
L1.3.1		Feasibility determination - completion of feasibility questionnaire	The activities associated with the completion of the feasibility assessment questionnaire covering the assessment of whether trial is consistent with institution's mission, research priorities and risk management	\$294.62 for completion of feasibility questionnaire required for a potential clinical trial	Based on the assumption that the PI and CTMC are the only two involved in protocol review and that the hourly rate (fully absorbed) of the PI is \$226.11/hour (as defined in item 2.6.1) and \$90.78/hour for CTMC (as defined in item 2.6.3). <ul style="list-style-type: none"> • Standard cost is calculated using the median of the gathered data.
L1.3.2		Feasibility determination - study site visit	The activities may include hosting a feasibility assessment visits by the trial sponsor and/or representative	\$675.96 for study site selection visit required by Sponsor organisation for a potential clinical trial	Based on the assumption that the PI, CTMC and at least one supporting department (usually the pharmacy) are involved and that the hourly rate (fully absorbed) of the PI is \$226.11/hour (as defined in item 2.6.1), \$90.78/hour for CTMC (as defined in item 2.6.3) and \$86.72/hour (blended hourly rate, based on the assumption that the involved personnel from supporting departments is either a hospital scientist (i.e. Grade 3/4 hospital scientist) and/or pharmacist (i.e. Grade 3/5 pharmacist)). <ul style="list-style-type: none"> • Standard cost is calculated using the median of the gathered data.
L1.3.3		Feasibility determination - budget negotiation and contract review	Based on the assumption that the PI, CRC, RGO and at least one supporting department are involved	\$755.52 for budget negotiation and contract review for a potential clinical trial	Based on the assumption that the PI, CTMC, at least one supporting department (usually the pharmacy) and personnel from the RGO are involved and that the hourly rate (fully absorbed) of the PI is \$226.11/hour (as defined in item 2.6.1), \$90.78/hour for CTMC (as defined in item 2.6.3), \$86.72/hour (blended hourly rate, based on the assumption that the involved personnel from supporting departments is either a hospital scientist (i.e. Grade 3/4 hospital scientist) and/or pharmacist (i.e. Grade 3/5 pharmacist) and \$70.95/hour for RGO staff based on the average salary for a research and governance officer is \$82,587 plus superannuation). <ul style="list-style-type: none"> • Standard cost is calculated using the median of the gathered data. • Assumes that the provided Sponsors' contract is either the standard Medicine Australia (MA), or MTA or other pre-approved agreement and includes the use of previously agreed or standard schedules (e.g. 4 and 7), if not, legal costs are incurred by the site (i.e. services either provided by internal or outsourced lawyer). This legal cost is not included in the standard cost.
L2.1	Ethics Approval	Preparation of the HREC application	The activities associated with the preparation and submission of the Human research ethics committee (HREC) application form (or equivalent) and supporting documentation which includes the protocol, participant information and consent form (PICF), recruitment and advertising materials, etc. Also includes revisions to applications in response to ethics committee requests for additional information and forwarding copies of relevant approvals (once obtained) and associated documentation to the trial funder/sponsor.	\$2,607.83 per clinical trial (i.e. per HREC application)	Based on the assumption that the PI and CTMC are the only two involved in a preliminary assessment and that the hourly rate (fully absorbed) of the PI is \$226.11/hour (as defined in item 2.6.1) and \$90.78/hour for CTMC (as defined in item 2.6.3). <ul style="list-style-type: none"> • Standard cost is calculated using the median of the gathered data. • As the data represents a mix of industry sponsored trials (where drafts of required documents are provided) as well as collaborative and investigator initiated trials (where de novo applications are prepared) this accounts for the large variation from min to 75th percentile. • The "max" value was due to the data gathered from the one paediatric site included in the study. Setting a differential standard cost for paediatric clinical trials at the 75th percentile was considered. However, as only one paediatric site was included in the sample, it was considered that there was insufficient evidence to set a differential standard cost for paediatric clinical trials at this stage, even though the gathered data suggests it would reflect a more realistic cost associated with the input time for such types of clinical trials.
L2.2		Ethics review	The activities associated with the review of the ethics application by the HREC, including the preparation of any requests for additional information and subsequent consideration of the material provided.	\$2,099.42 per clinical trial application	Based on the assumption that there are eight members on the HREC and the included all mix are: 1x chairperson, 1x legal background, 2x medical backgrounds, 2x scientific and/or allied health discipline backgrounds, 1x ethics officer, 1x lay members. <ul style="list-style-type: none"> • Based on the assumption that each HREC application is reviewed in detail by a primary and secondary reviewer. • Standard cost is calculated using the median for all gathered data except for the data related to the ethics officer which is based on the 75th percentile. • It is recognised that although most members of HREC do not receive a sitting fee, a standard cost has been calculated on cost net fees incurred.

Note: IHPA full absorbed rate 33%

Cost Types



- Feasibility

Activity prior to project approval

- Indirect (non-project specific)

Salaries, training, research equipment, administration, utilities

- Direct (project specific)

Non-salary costs directly related to project

SSA budget



With this much grant money, only experiment we can do is "flip a coin"!

Review procedures/participant visits

- Protocol schedule
- Sponsor schedule

Code	Procedure	Qty	OH	Budget	SV	D1	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W14	W18	W22	W25	Total (AUD)		
INCON	Informed consent	1	✓	100.00	100.00																	\$ 100.00	
99211	Vital sign measurements	53	✓	30.00		150.00	150.00	150.00	150.00	150.00	150.00	150.00	150.00	150.00	150.00	30.00	30.00	30.00				\$ 1,590.00	
80299	PK blood draw (collected pre-dose and 4 hours post-dose)	28	✓	20.00		40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00			\$ 560.00	
S0823	6 Minute Walk Test (6MWT)	9	✓	100.00	200.00	100.00					100.00					100.00	100.00	100.00	100.00	100.00		\$ 900.00	
93451	Right heart catheterization	2	✓	1,000.00	1,000.00																	\$ 2,000.00	
R3451	Right heart catheterization interpretation/report	2	✓	300.00	300.00														300.00			\$ 600.00	
93000	Electrocardiogram, 12 lead: Includes tracing, interpretation and report	26	✓	75.00	75.00	150.00	150.00	150.00	150.00	150.00	150.00	150.00	150.00	150.00	150.00	75.00	75.00	75.00	75.00	75.00		\$ 1,950.00	
T6416	Blood draw for clinical laboratory tests, HIV, HBsAg, HCV, serum pregnancy test (for women), and BNP/NT-pro BNP	10	✓	50.00	50.00	50.00		50.00			50.00				50.00	50.00	50.00	50.00	50.00	50.00		\$ 500.00	
93307	Echocardiography	1	✓	150.00	150.00																	\$ 150.00	
R3307	Echocardiogram interpretation and report	1	✓	50.00	50.00																	\$ 50.00	
99205	Screening/Week 25 - comprehensive physical exam, medical and social history, PAH history, vital signs and WHO/NHYA functional class	2	✓	350.00	350.00																350.00	\$ 700.00	
78580	IV scan	1	✓	450.00	450.00																	\$ 450.00	
R8580	IV scan interpretation and report	1	✓	100.00	100.00																	\$ 100.00	
CONMD	Concomitant medication monitoring	16	✓	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	\$ 800.00	
ADEV7	Adverse event monitoring	16	✓	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	\$ 800.00	
94150	Pulmonary function test (PFT)	1	✓	150.00	150.00																	\$ 150.00	
99212	Week 22 - physical exam, vital sign measurements, and WHO/NHYA functional class	1	✓	200.00																200.00		\$ 200.00	
S0074	WHO/NHYA functional class assessment	13	✓	30.00		30.00	30.00	30.00	30.00	30.00	30.00	30.00	30.00	30.00	30.00	30.00	30.00	30.00				\$ 390.00	
Procedures Sub Total (AUD)					3,075.00	620.00	470.00	520.00	470.00	470.00	620.00	470.00	470.00	470.00	520.00	425.00	425.00	425.00	1,865.00	675.00		\$ 11,990.00	
Code	Non Procedure	Qty	OH	Budget	SV	D1	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W14	W18	W22	W25			
NP008	Patient Reimbursement - Per Visit	16		50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	\$ 800.00	
NP021	Study Coordinator - Per Visit	16		80.00	80.00	80.00	80.00	80.00	80.00	80.00	80.00	80.00	80.00	80.00	80.00	80.00	80.00	80.00	80.00	80.00	80.00	\$ 1,280.00	
Non Procedures Sub Total (AUD)					130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	130.00	\$ 2,080.00	
Code	Conditional Procedure	Qty	OH	Budget	SV	D1	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W14	W18	W22	W25			
81025	Urine pregnancy test	1	✓	20	0.00	20.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	\$ 20.00	
WA Health Infrastructure Fee 25%							\$769.00	\$155.00	\$118.00	\$130.00	\$118.00	\$155.00	\$118.00	\$118.00	\$130.00	\$106.00	\$106.00	\$106.00	\$106.00	\$106.00	\$106.00	\$106.00	\$ 3,000.00
Total Cost Per Visit with Overhead(AUD)					\$3,974.00	\$905.00	\$718.00	\$780.00	\$718.00	\$718.00	\$905.00	\$718.00	\$718.00	\$718.00	\$718.00	\$780.00	\$661.00	\$661.00	\$661.00	\$2,461.00	\$974.00	\$ 17,070.00	
10% Withheld for Final Study Payment					\$397.40	\$90.50	\$71.80	\$78.00	\$71.80	\$71.80	\$90.50	\$71.80	\$71.80	\$71.80	\$71.80	\$78.00	\$66.10	\$66.10	\$66.10	\$246.10	\$97.40	\$1,707.00	
VISIT PAYMENT SCHEDULE (AUD)					\$3,576.60	\$814.50	\$646.20	\$702.00	\$646.20	\$646.20	\$814.50	\$646.20	\$646.20	\$646.20	\$646.20	\$702.00	\$594.90	\$594.90	\$594.90	\$2,214.90	\$876.60	\$15,363.00	

Identify rates for salary based procedures

- WA Health Research Budget Template Nov 2015

<http://ww2.health.wa.gov.au/Health-for/Researchers-and-educators/Research-governance>

- Awards

<http://www.health.wa.gov.au/AwardsAndAgreements>

- IHPA Standard cost items

Note: IHPA costs are often bundled (e.g. start up) with fully absorbed salaries (includes 33% overhead, can /1.33 to remove).

Do not add overheads to these items.

WA Award Rates used in Costing Template

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
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	
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

Calculate salary, oncosts, overhead

HCN Health Accounting Manual (HAM) for rates:

- On-costs only for staff employed directly by WA Health;
- Internal rate: 23.25%
- External rate: Non-medical staff 30.25% + Medical staff 40.25%

Oncosts:

- 0% (NHMRC, charities, DoH)
- 10%
- 25% (>\$10M company)

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	
			WA Health Hourly Rates (fully absorbed - direct, oncosts & indirect costs)	IHPA Hourly Rate (fully absorbed - direct, oncosts & indirect costs)
Clinical Resources Positions	WA Health Salary Level/Grade	WA Health Hourly Rates (direct & oncosts)		
Investigator time – Principal investigator	AMA Yr 9	\$ 155.64	\$ 194.55	\$ 226.11
Investigator time – sub/co- investigator	AMA Yr 5	\$ 128.04	\$ 160.06	\$ 199.11
Research nurse time	ANF Level 2.4	\$ 57.36	\$ 71.70	\$ 74.79
Clinical research coordinator (non-research nurse) time – equivalent to Clinical Trials Coordinator (CTC)	HSU G-6.3	\$ 60.10	\$ 75.12	\$ 82.74
Clinical research coordinator (non-research nurse) time – equivalent to Clinical Trials Manager (CTM)	ANF SRN Level 3	\$ 69.06	\$ 86.32	\$ 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	\$ 64.58	\$ 80.72	\$ 90.78
Interpreter services		\$ -	\$ -	\$ 53.91

Oncosts Cost Rate:

23.25%

Indirect (overhead) Cost Rate:

25%

Per participant budget (Simple)

Procedures	Investigator Time (no overhead)	Research Nurse Time (no overhead)	CTC Time (no overhead)	CM Time (no overhead)	Calculated Cost based on Time and Salary	Calculated Cost based on Time and Salary (including overhead)
Screening	5	5	1		\$ 1,125.10	\$ 1,406.37
Week 0	3	5	1		\$ 813.82	\$ 1,017.27
Week 2	1	3	0		\$ 327.72	\$ 409.65
Week 4	2	4	0		\$ 540.72	\$ 675.90
Week 6	1	3	0		\$ 327.72	\$ 409.65
Week 8	1	4	0		\$ 385.08	\$ 481.35
Week 10	3	8	1		\$ 985.90	\$ 1,232.38
Week 12	1	4	0		\$ 385.08	\$ 481.35
Week 14	0	6	1		\$ 404.26	\$ 505.33
SUB TOTAL	\$ 2,645.88	\$ 2,409.14	\$ 240.39	\$ -	\$ 5,295.41	\$ 6,619.26
Unscheduled visit	1	2	1		\$ 330.46	\$ 413.07
Early withdrawal from treatment	2	5	1		\$ 658.18	\$ 822.72
12 Week Safety - week 6	0	1	1		\$ 117.46	\$ 146.82
Week 12/ early termination	2	3	1		\$ 543.46	\$ 679.32
Unscheduled visit	1	1	1		\$ 273.10	\$ 341.37
TOTAL	\$ 3,579.72	\$ 3,097.47	\$ 540.87	\$ -	\$ 7,218.06	\$ 9,022.58

Create a breakdown from the schedule of events in the Protocol to calculate amount per visit/procedure or individual salaries per total visits/procedures

You can enter into RGS Budget as individual visits per participant

OR

You can enter into RGS Budget as individual personnel salaries per participant

Per participant budget (Complex) – Normal Procedures

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

Procedures	Enter time in hours each person spends on each procedure				Enter number of times procedure occurs per visit (usually 1)														Subtotal							
	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		
Informed consent	1	1	0	0	\$ 213.00	1	\$ 213.00		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -	
Vital signs	0	1	0	0	\$ 57.36	1	\$ 57.36	1	\$ 57.36	1	\$ 57.36	1	\$ 57.36	1	\$ 57.36	1	\$ 57.36	1	\$ 57.36	1	\$ 57.36	1	\$ 57.36	1	\$ 57.36	
Medical history	1	1	1	1	\$ 273.10	1	\$ 273.10	1	\$ 273.10		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -	
Physical exam	1	1	0	0	\$ 213.00	1	\$ 213.00	1	\$ 213.00		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -	
ECG	1	0	0	0	\$ 155.64	1	\$ 155.64	1	\$ 155.64		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -	
Adverse event monitoring	0	3	1	1	\$ 232.18		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -		\$ -	
Blood draw	1	1	0	0	\$ 213.00	1	\$ 213.00	0	\$ -	1	\$ 213.00	1	\$ 213.00	1	\$ 213.00	1	\$ 213.00	1	\$ 213.00	1	\$ 213.00	1	\$ 213.00	1	\$ 213.00	
Questionnaire	0	1	0	0	\$ 57.36		\$ -	1	\$ 57.36	1	\$ 57.36	1	\$ 57.36	1	\$ 57.36	1	\$ 57.36	1	\$ 57.36	1	\$ 57.36	1	\$ 57.36	1	\$ 57.36	
Data entry	0	1	0	0	\$ 57.36		\$ -	1	\$ 57.36		\$ -	1	\$ 57.36		\$ -	1	\$ 57.36		\$ -	1	\$ 57.36		\$ -	1	\$ 57.36	
Subtotal	\$ 778.20	\$ 573.61	\$ 120.19	\$ -	\$ 1,472.00		\$ 1,125.10		\$ 813.82		\$ 327.72		\$ 540.72		\$ 327.72		\$ 385.08		\$ 985.90		\$ 385.08		\$ 404.26		\$ 5,295.41	
Unscheduled Procedures																										
Unscheduled visit	1	2	1	1	\$ 330.46																					
Early withdrawal from treatm	2	5	1	1	\$ 658.18																					
12 Week Safety - week 6	0	1	1	1	\$ 117.46																					
Week 12/ early termination	2	3	1	1	\$ 543.46																					
Unscheduled visit	1	1	1	1	\$ 273.10																					
Subtotal	\$ 933.84	\$ 688.33	\$ 300.48	\$ -	\$ 1,922.65																					
TOTAL	\$ 1,712.04	\$ 1,261.93	\$ 420.68	\$ -	\$ 3,394.65																					
Total salaries per visit																										
Investigator	5	\$ 778.20	3	\$ 466.92	1	\$ 155.64	2	\$ 311.28	1	\$ 155.64	1	\$ 155.64	3	\$ 466.92	1	\$ 155.64	0	\$ -								\$ 2,645.88
Research Nurse		\$ 286.80	5	\$ 286.80	3	\$ 172.08	4	\$ 229.44	3	\$ 172.08	4	\$ 229.44	8	\$ 458.88	4	\$ 229.44	6	\$ 344.16								\$ 2,409.14
CTC	1	\$ 60.10	1	\$ 60.10	0	\$ -	0	\$ -	0	\$ -	0	\$ -	1	\$ 60.10	0	\$ -	1	\$ 60.10								\$ 240.39
CM	0	\$ -	0	\$ -	0	\$ -	0	\$ -	0	\$ -	0	\$ -	0	\$ -	0	\$ -	0	\$ -								\$ -
TOTAL																										\$ 5,295.41

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.

Per participant budget (Complex) – 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	Subtotal	Total	Cost based on Time and Salary (including overhead)
Informed consent	1	1	0		\$ 213.00		\$ -		\$ -		\$ -		\$ -		\$ -	\$ 213.00	\$ 266.25	
Vital signs	0	1	0		\$ 57.36		\$ -		\$ -		\$ -		\$ -		\$ -	\$ 57.36	\$ 645.31	
Medical history	1	1	1		\$ 273.10		\$ -		\$ -		\$ -		\$ -		\$ -	\$ 273.10	\$ 682.74	
Physical exam	1	1	0		\$ 213.00		\$ -		\$ -		\$ -		\$ -		\$ -	\$ 213.00	\$ 798.75	
ECG	1	0	0		\$ 155.64		\$ -		\$ -		\$ -		\$ -		\$ -	\$ 155.64	\$ 778.20	
Adverse event monitoring	0	3	1		\$ 232.18		\$ -		\$ -		\$ -		\$ -		\$ -	\$ 232.18	\$ 580.45	
Blood draw	1	1	0		\$ 213.00		\$ -		\$ -		\$ -		\$ -		\$ -	\$ 213.00	\$ 1,863.76	
Questionnaire	0	1	0		\$ 57.36		\$ -		\$ -		\$ -		\$ -		\$ -	\$ 57.36	\$ 573.61	
Data entry	0	1	0		\$ 57.36		\$ -		\$ -		\$ -		\$ -		\$ -	\$ 57.36	\$ 430.20	
Subtotal	\$ 778.20	\$ 573.61	\$ 120.19	\$ -	\$ 1,472.00		\$ -		\$ -		\$ -		\$ -		\$ -	\$ 5,295.41	\$ 6,619.26	
Unscheduled Procedures																		
Unscheduled visit	1	2	1		\$ 330.46	1	\$ 330.46		\$ -		\$ -		\$ -		\$ -	\$ 330.46	\$ 413.07	
Early withdrawal from treatment	2	5	1		\$ 658.18		\$ -	1	\$ 658.18		\$ -		\$ -		\$ -	\$ 658.18	\$ 822.72	
12 Week Safety - week 6	0	1	1		\$ 117.46		\$ -		\$ -	1	\$ 117.46		\$ -		\$ -	\$ 117.46	\$ 146.82	
Week 12/ early termination	2	3	1		\$ 543.46		\$ -		\$ -		\$ -	1	\$ 543.46		\$ -	\$ 543.46	\$ 679.32	
Unscheduled visit	1	1	1		\$ 273.10		\$ -		\$ -		\$ -		\$ -	1	\$ 273.10	\$ 273.10	\$ 341.37	
Subtotal	\$ 933.84	\$ 688.33	\$ 300.48	\$ -	\$ 1,922.65		\$ 330.46		\$ 658.18		\$ 117.46		\$ 543.46		\$ 273.10	\$ 1,922.65	\$ 2,403.31	
TOTAL	\$ 1,712.04	\$ 1,261.93	\$ 420.68	\$ -	\$ 3,394.65											\$ 7,218.06	\$ 9,022.58	
Total salaries per visit																		
Investigator	1	2	1		\$ 155.64	1	\$ 155.64	2	\$ 311.28	0	\$ -	2	\$ 311.28	1	\$ 155.64	\$ 933.84	\$ 3,579.72	\$ 4,474.65
Research Nurse	2	5	1		\$ 114.72		\$ 229.44	5	\$ 573.60	1	\$ 114.72	3	\$ 344.16	1	\$ 114.72	\$ 688.33	\$ 3,097.47	\$ 3,871.84
CTC	1	1	1		\$ 60.10		\$ 60.10	1	\$ 60.10	1	\$ 60.10	1	\$ 60.10	1	\$ 60.10	\$ 300.48	\$ 540.87	\$ 676.09
CM	0	0	0		\$ -		\$ -	0	\$ -	0	\$ -	0	\$ -	0	\$ -	\$ -	\$ -	\$ -
TOTAL																\$ 1,922.65	\$ 7,218.06	\$ 9,022.58

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.

Research Department SSA costs

Service/Support/Item provided (C)	Cost per test/item (D)	Cost per participant (E)	Total costs for the site (F)	\$ Amount of funding by sponsor or funder (G)	\$ Amount of in-kind support from the site or others (H)
Proposed number of participants per site:		5	Project timeframe in years		4
number of participants per site to give a figure in (F).					
Overhead 25%			\$9,022.58	\$ 11,966.25	\$ -
Investigator time – Principal investigator		\$ 3,579.72	\$ 17,898.61	\$ 47,865.00	\$ -
Research nurse time		\$ 3,097.47	\$ 15,487.35	\$ -	\$ -
Clinical research coordinator (non-research nurse) time – equivalent to Clinical Trials Coordinator (CTC)		\$ 540.87	\$ 2,704.35	\$ -	\$ -

**Total Cost =
test/participant x time x
no. of participants**

16.3 Site/Region Project Budget							
Research & Supporting Departments Name (A)	Head of Department (or equivalent) must complete and sign Declaration (B)	Service/Support/Item provided (C)	Cost per test/item (D)	Cost per participant (E)	Total costs for the site (F)	\$ Amount of funding by sponsor or funder (G)	\$ Amount of in-kind support from the site or others (H)
Site: Fiona Stanley Hospital		Proposed number of participants per site:		5	Project timeframe in years		4
If (E) is completed then this is multiplied by Proposed number of participants per site to give a figure in (F).							
Research Department							
Gastroenterology	John Smith	Overhead 25%			\$9,022.58	\$ 11,966.25	\$ -
		Investigator time – Principal Investigator		\$ 3,579.72	\$ 17,898.61	\$ 47,865.00	\$ -
		Research nurse time		\$ 3,097.47	\$ 15,487.35	\$ -	\$ -
		Clinical research coordinator (non-research nurse) time – equivalent to Clinical Trials Coordinator (CTC)		\$ 540.87	\$ 2,704.35	\$ -	\$ -
		Preparation of the HREC application - Start Up Fee	\$ 2,600.00		\$ 2,600.00	\$ 2,600.00	\$ -
		Preparation of the SSA application by the project team - Start Up Fee	\$ 400.00		\$ 400.00	\$ 400.00	\$ -
		Pre-screening activity	\$ 166.00		\$ 830.00	\$ 530.00	\$ -
		Screen Failures (1:2)	\$ 1,414.00		\$ 1,414.00	\$ 1,414.00	\$ -
		Discontinued or Early Termination Payments based on completed visits	\$ -		\$ -	\$ -	\$ -
		Trial specific equipment setup and maintenance	\$ 800.00		\$ 800.00	\$ 800.00	\$ -
		Handheld Computer (edriary)	\$ 250.00		\$ 250.00	\$ 250.00	\$ -
		Laptop	\$ 515.00		\$ 515.00	\$ 515.00	\$ -
		Archiving Fee (15 years)	\$ 2,000.00		\$ 2,000.00	\$ 2,000.00	\$ -
		Reconsenting Fee	\$ 113.00		\$ 113.00	\$ 84.00	\$ -
		Central Labs (Haematology, Chemistry)	\$ 28.05	\$ 28.05	\$ 140.25	\$ 31.00	\$ -
		Central Labs (Anti-therapeutic antibody, CRP) includes Collection, Preparation and Processing	\$ 34.00	\$ 34.00	\$ 170.00	\$ 64.00	\$ -
		MCS	\$ 29.00	\$ 29.00	\$ 145.00	\$ 145.00	\$ -
		Partial MCS	\$ 19.00	\$ 19.00	\$ 95.00	\$ 95.00	\$ -
		Colonic biopsy (histopathological confirmation of UC)	\$ 375.00	\$ 375.00	\$ 1,875.00	\$ 1,875.00	\$ -
		Biopsy; Staining and preparation of the slides including shipping and handling	\$ 89.00	\$ 89.00	\$ 445.00	\$ 445.00	\$ -
		Colonic biopsy (CMV)	\$ 104.00	\$ 104.00	\$ 520.00	\$ 520.00	\$ -
		Colonoscopy, with biopsy	\$ 1,066.00	\$ 1,066.00	\$ 5,330.00	\$ 5,330.00	\$ -
		Sigmoidoscopy, with biopsy	\$ 404.00	\$ 404.00	\$ 2,020.00	\$ 2,020.00	\$ -
					\$64,775.14	\$78,949.25	\$ -

Additional research department costs

- IHPA standard costs
- Department costs
- Medicare Benefits Schedule

<http://www9.health.gov.au/mbs/search.cfm>

Trial Initiation	Trial specific equipment setup and maintenance	The activities associated with the hire, purchase and/or receipt from the sponsor of any equipment (including IT infrastructure) required for the purposes of conducting the clinical trial. Includes the required setup/customisation/commissioning of the equipment so that it is suitable for use in the clinical trial, as well as local maintenance of the equipment throughout the trial.	\$85.04 per piece of trial equipment
Ethics Approval	Preparation of the HREC application	The activities associated with the preparation and submission of the human research ethics committee (HREC) application form (or equivalent) and supporting documentation which includes the protocol, participant information and consent form (PICF), recruitment and advertising materials, etc. Also	\$2,607.83 per clinical trial (i.e. per HREC application)
	Ethics review	The activities associated with the review of the ethics application by the HREC, including the preparation of any requests for additional information and subsequent consideration of the material provided.	\$2,099.42 per clinical trial application
Site-specific assessment	Preparation of the SSA application by the project team	The activities associated with the preparation and submission of the Site Specific Assessment (SSA) form (or equivalent) by the PI or project team, which include completion of the	\$398.69 per SSA application
	Site processing and review	The activities associated with the processing of country specific regulatory documents (e.g. the Clinical Trial Notification (CTN) Scheme form), insurance and indemnity documents, safety and/or biosafety reports, trial agreements, requesting,	\$264.71 per SSA application processed

Supporting Departments

16.3 Site/Region Project Budget							
Research & Supporting Departments Name (A)	Head of Department (or equivalent) must complete and sign Declaration (B)	Service/Support/Item provided (C)	Cost per test/item (D)	Cost per participant (E)	Total costs for the site (F)	\$ Amount of funding by sponsor or funder (G)	\$ Amount of in-kind support from the site or others (H)
Site:	Fiona Stanley Hospital	Proposed number of participants per site:		5	Project timeframe in years		4
If (E) is completed then this is multiplied by Proposed number of participants per site to give a figure in (F).							
Supporting Departments							
Pharmacy	Jane Doe	Set Up Fee	\$ 1,200.00		\$ 1,200.00	\$ 1,200.00	\$ -
		Close Out Fee	\$ 400.00		\$ 400.00	\$ 400.00	\$ -
		Archive Fee	\$ 150.00		\$ 150.00	\$ 150.00	\$ -
		Annual Administration Fee	\$ 500.00		\$ 2,000.00	\$ 2,000.00	\$ -
		Annual Storage Fee	\$ 100.00		\$ 400.00	\$ 400.00	\$ -
		Dispensing Fee	\$ 45.00	\$ 180.00	\$ 900.00	\$ 900.00	\$ -
		Remote Monitoring Fee - \$100 per instance	\$ 100.00		\$ 100.00	\$ 100.00	\$ -
					\$ 5,150.00	\$ 5,150.00	\$ -

Recruitment ceases Jul 2017 competitive
 Anticipated 5 patients
 Study costed for 4 years
 CTRA states quarterly invoicing, however put through monthly
 Other cost at \$150 is the archiving fee at the end of the study
 Annual Fee at \$600 is storage and annual together
 All IP supplied by sponsor
 Archive fee to be waived if filed with site files

Service Agreement

Trial Charges (\$)	
✓ Trial Set Up	\$1,200.00
Remote Monitoring	
Drug Transfer	
✓ Close Out Cost	\$400.00
✓ Annual Fee	\$600.00
IXRS fee	
After Hours Cost	
✗ Other Costs	\$150.00
Patients	5
✓ Cost/dispensing	\$45.00
Dispensings/patient	4
Cost/patient	\$180.00
Total trial cost \$	\$5,050.00

Review funding agreements

Clinical Trial Research Agreement

Schedule 2 Payments

BUDGET AND PAYMENT SCHEDULE

Treatment Period Study Week

Visit	Amount (AUD) Includes 25% Institutional OH
Screening	1,414
Week 0	1,076
Week 2	476
Week 4	730
Week 6	458
Week 8	531
Week 10	1,331
Week 12	468
Week 14	533
Total	7,017
Unscheduled Visit	448
Early Withdrawal from Treatment	858
12- Week Safety Follow Up Visit	Amount (AUD) Includes 25% Institutional OH
Week 6	161
Week 12 / Early Termination	745
Unscheduled Visit	344

Research/Supporting Department SSA funding

Neurology	Mary Kane	Neurologist - Per Hour	\$ 190.00		\$ 950.00	\$ 950.00	\$ -
		Lumbar puncture	\$ 299.00		\$ 1,495.00	\$ 1,495.00	\$ -
		Neurologic examination	\$ 116.00		\$ 580.00	\$ 580.00	\$ -
		Cerebrospinal fluid (CSF) analysis; includes lab handling for shipment to central lab	\$ 95.00		\$ 475.00	\$ 475.00	\$ -
					\$ 3,500.00	\$ 3,500.00	\$ -
Imaging	Sally Field	Brain MRI with contrast, includes interpretation and report	\$ 2,834.00		\$ 14,170.00	\$ 14,170.00	\$ -
		Brain MRI without contrast, includes interpretation and report	\$ 2,155.00		\$ 10,775.00	\$ 10,775.00	\$ -
		Chest X-ray, includes interpretation and report	\$ 148.00		\$ 740.00	\$ 740.00	\$ -
					\$ 25,685.00	\$ 25,685.00	\$ -
Ethics Office	SMHS REGU	Ethics review	\$ 3,500.00		\$ 3,500.00	\$ 3,500.00	\$ -
Research Governance Office	SMHS REGU	Site processing and review	\$ 3,500.00		\$ 3,500.00	\$ 3,500.00	\$ -
					\$ 7,000.00	\$ 7,000.00	\$ -
Total for site					\$107,845.14	\$122,019.25	\$ -
Total site balance = (G+H) - F	\$14,174.11						
Add additional rows and sites as required.							
Total for all sites							
Total for all sites balance = (G+H) - F	\$14,174.11						
16.4 If costs are not covered by the sponsor explain how the costs will be covered or explain how the site will benefit from the research.						N/A	

Funder Type

16.1 Site(s) Project Funding/Support					
16.1.1 Has this project received/or has confirmed research funding (including investigator remuneration or in-kind support)? Yes					
16.1.1.1 If No, will the investigators be applying for research funding (including in-kind support)? <i>Not answered as above question Yes</i>					
16.1.2 Indicate how the project will be/or is intended to be funded/supported at the site(s). If there are multiple sites in a 'group of sites' listed in 1.3.1, indicate which site is receiving the funding or add more tables if funding is being received at multiple sites.					
16.1.2.1 Site Name: Fiona Stanley Hospital					
Type of funding	Funder name	Amount of funding \$ for the site*	Amount of in-kind support in \$ value	Funding is confirmed/received or being sought	
				Confirmed	Sought
Commercially sponsored	ABC Company	\$ 122,019.25	\$ -	X	
Non-commercial sponsored (e.g. collaborative groups)					
Grants (e.g. NHMRC)					
Donations/Bequests					
Internal department funds					
Other (specify)					
Sub total for site		\$ 122,019.25	\$ -		
Total Funding for Site**		\$ 122,019.25			
For a 'group of sites' add more tables as required for each site.					
Total Funding for All Sites***		\$ 122,019.25			
* This amount is based on the recruitment of the <u>total</u> number of participants listed in 5.3 over the time period of the project in 1.5.3. <i>Proposed Number of Participants per Site: 5</i>					
** This equates to the \$ amount of funding plus in-kind support at the site.					
*** This equates to the total \$ amount of funding plus in-kind support for all sites covered by this SSA Form. It should be the same as the total of columns (G) + (H) for all sites in 16.3.					
16.2 Will participants receive any payment or expenses for participation in the research? No					
16.2.1 If Yes, give details. <i>Not answered as above question No</i>					

Example and Questions

