USER GUIDE: NSW BUDGET COSTING TOOL

February 2018 (Version 1.0)

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Document Revisions

Date	Version Number	Document Changes
27/10/2017	0.1	Initial draft
17/11/2017	0.2	Completion of post-consultation revisions
XX/02/2017	V1	Final changes for release version

1. Purpose

The NSW Costing Tool (the Tool) is a Microsoft Excel based spreadsheet[1] developed to facilitate the process of study costing for research being conducted by NSW Public Health Organisations (PHOs).

The Tool[2] has been developed so that those responsible for costing a study can identify where costs may be incurred so that the process can be completed quickly and accurately, and those that review costings can make an accurate assessment regarding the financial and resource implication of conducting the study.

Use of the tool will help to ensure to:

- provide a consistent framework and methodology for cost calculations;
- support swift local site budget negotiation and study set-up;
- ensure that a research project does not fail simply because the time or resource required for completion was underestimated (funding shortfall);
- That departments conducting research have the information they need to manage their research budgets.

The Tool is designed to be used with the standard model agreements that can be found on the NSW Health Website.

[1] The use of this tool requires some basic knowledge of Excel. Those with no experience with Excel may need training.
[2] This tool will be enhanced over time and feedback would be welcome.

2. Scope

The Tool is primarily designed for the costing *of commercial and non-commercial* clinical trials where the PHO is a participating site so that the site can be aware of the true cost the study to the institution. This information can then be used to inform contract negotiation.

Note: The Tool can be used to cost other study designs where the PHO is a participating centre. It can also be adapted to cost investigator-led studies (where the site is the sponsor), although the Tool does not pre-populate sponsor-related or trial centre management costs such as database building, case report form creation, statistical analysis or monitoring.

3. Cost Calculation Methodology

The Tool provides a framework for transparent cost display and calculation to support swift local site budget negotiation using fair market value principles.

The spreadsheet values are based on staff rates to enable input of study specific staff time required undertake the procedures and investigations required by the trial; their frequency, as well as any set-up or additional charges. The worksheets within the Tool reduce the study protocol to a series of chargeable events, each of which (if not agreed as standard of care) has a price attached. The tool has embedded formulae to calculate per patient costs.

3.1 Staff Costs

NSW Award Rates for staff are available on the NSW Health Remuneration and Conditions website, which can be found here: http://www.health.nsw.gov.au/careers/conditions/Pages/a.aspx

Staff indirect costs (on-costs) are then added to the rate to provide a final full staff rate. Staff indirect costs cover elements such as leave entitlements, superannuation, workers compensation.

3.2 Overhead Margin

The overhead margin covers the cost of site infrastructure which allows clinical trial activity to take place. It enables reimbursement of those tasks which cannot always be attributed to a specific study procedure or investigation such as the setup of finance systems and IT systems.

In addition, investment in research requires the long term commitment of all stakeholders and investment in infrastructure within PHOs to maintain a research capacity to the benefit of all research partners (e.g. support services within research offices, trial awareness activities, development of a research-ready workforce). The overhead margin is added to direct staff costs and investigation costs.

3.3 Reference Sources for Pricing

Although costs are not provided with the Tool, suggested ranges across NSW and references to other resources have been provided to assist with costings and suggested ranges.

- The Independent Hospital Pricing Authority (IHPA)[3] has produced a list of standard costs associated with conducting clinical trials can be used as a guide to cost all types of clinical trial. This table of standard costs can be referenced and used on an activity basis, for example, for some items the frequency of occurrence of an activity can be used together with the standard cost for that activity to provide a more accurate measure of the trial specific cost.

- The Medical Benefits Scheme (MBS) 2017 ranges (which can be adjusted to include overheads) a comprehensive list for all research.

- The Australian Medical Association (AMA) List of Medical Services and Fees - 1 November 2016 (Members Only) contains fees which cover doctors' work and practice costs.

3.4 Factoring for Annual Inflation

For longer term studies, this Tool does not automatically account for inflation. Instead, it is recommended that the Overhead rate is adjusted to account for an annual inflation rate of approximately 2–3 percent for each year.

3.5 Standard of Care

Some procedures or investigations included in a clinical trial may be deemed standard of care and therefore not chargeable when these procedures or investigations form part of a clinical trial. Any research associated costs additional to the standard procedures (e.g. ECG uploading to an additional system for Sponsor receipt) are still chargeable.

Note: Standard of Care will vary across sites and the site should determine if any procedures or investigations are standard of care.

4. Worksheets

The worksheets enable the input of study related costs such as the staffing, procedures, investigations, as well as any set-up or additional charges. Within the Tool, some of the worksheets require the input of information that is used for costing a study and others provide instructional, summary and reference information. These worksheets are titled as follows:

- Tab 1 – Overview (general information)
- Tab 2 - Trial Information
- Tab 3 - Per Patient Budget
- Tab 4 - Additional Itemised Activities
- Tab 5 – Pharmacy

[3] The Independent Hospital Pricing Authority (IHPA) is a government agency established under Commonwealth legislation on 15 December 2011.

- Tab 6 - Setup and Other Costs
- Tab 7 – Summary
- Tab 8 – Item Lists

Note: All values calculate automatically and the formulae behind the cells are locked. You must click out of the cell for the calculation to appear. To remove data from a cell, right click the mouse and select 'delete'.

5. Points to Consider Before Using the Tool

- Ensure that you have a final (or near final) protocol before costing a study to avoid repeated amendments.
- Ensure all study protocol requirements are clearly identified and understood and that all activities that are standard of care have been identified.
- Ensure transparency during the costing process, i.e. the work performed can be clearly linked to the fee that gets paid and that all rates levels used and assumptions made are documented and justifiable.
- Use a standard pricing source (organisations encouraged to develop a standard tariff that is applied across trials)
- Be aware that study costs can vary depending on therapeutic area, site type and phase/stage and patient populations (staff time requirements for trials involving children are generally longer)
- Identify all non-procedural activities which are linked to visits such as data entry, Principal Investigator study oversight.

6. Downloading the Template

The NSW Costing Tool can be found on the XX website and will need to be downloaded as follows:

1. Open the NSW Budget Costing Tool
2. Save a copy of the template to your local network ready to enter costing information for your individual project

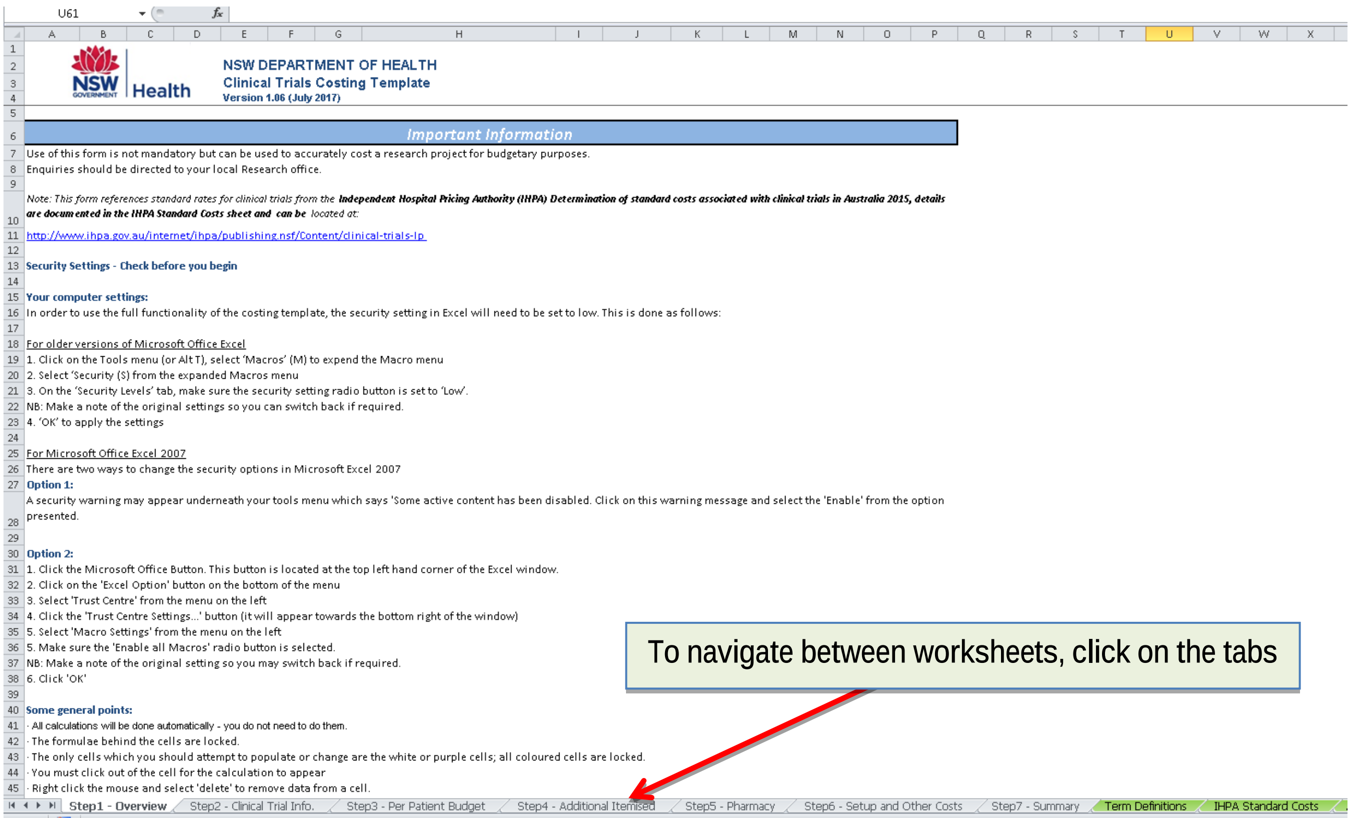
In order to use the full functionality of the costing template, the security setting[4] in Microsoft Excel will need to be set to low as described on the 'Overview' tab.

[4] Make a note of the original settings so you can switch back if required.

7. Step by Step Worksheet Completion

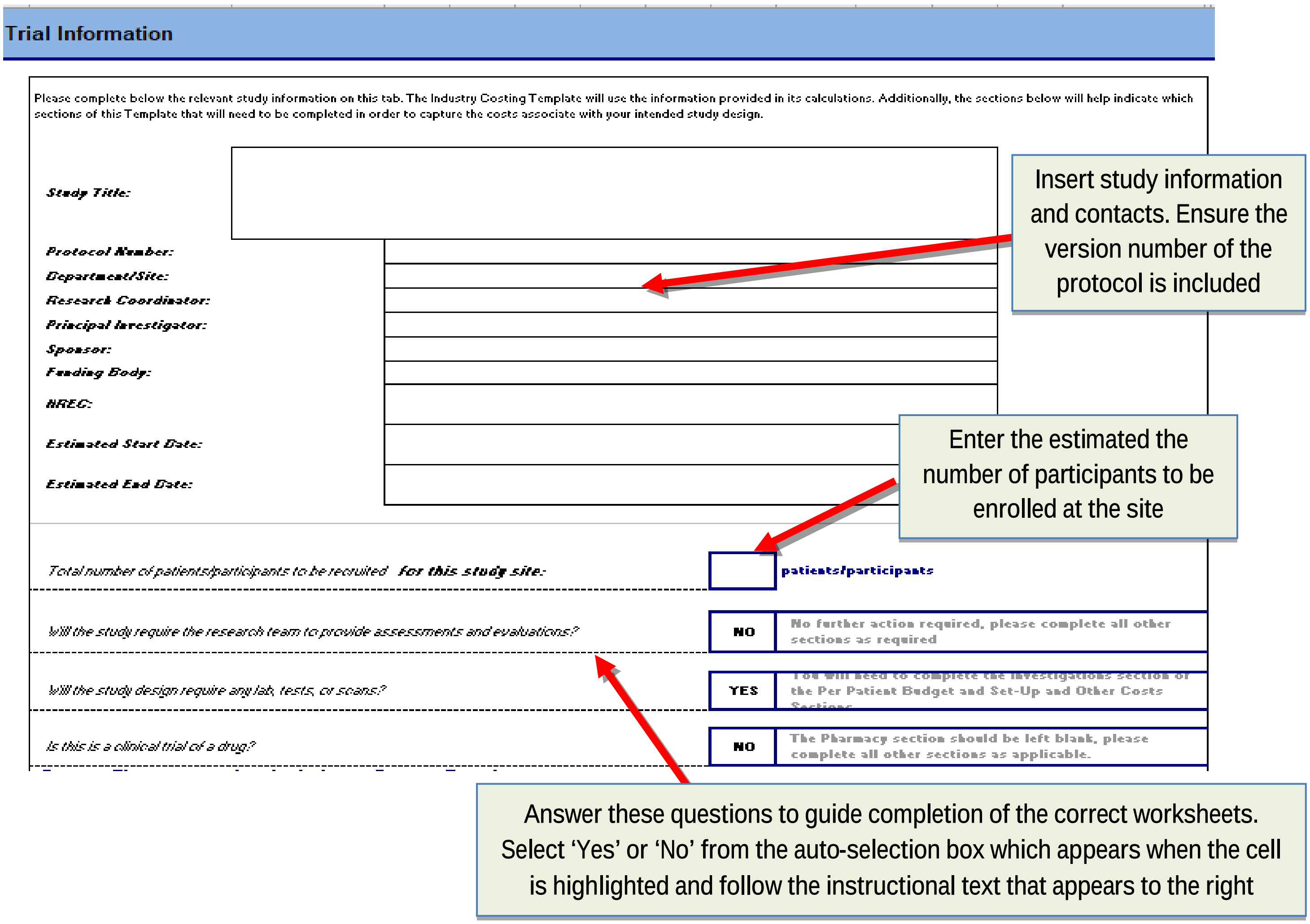
7.1 Overview Worksheet

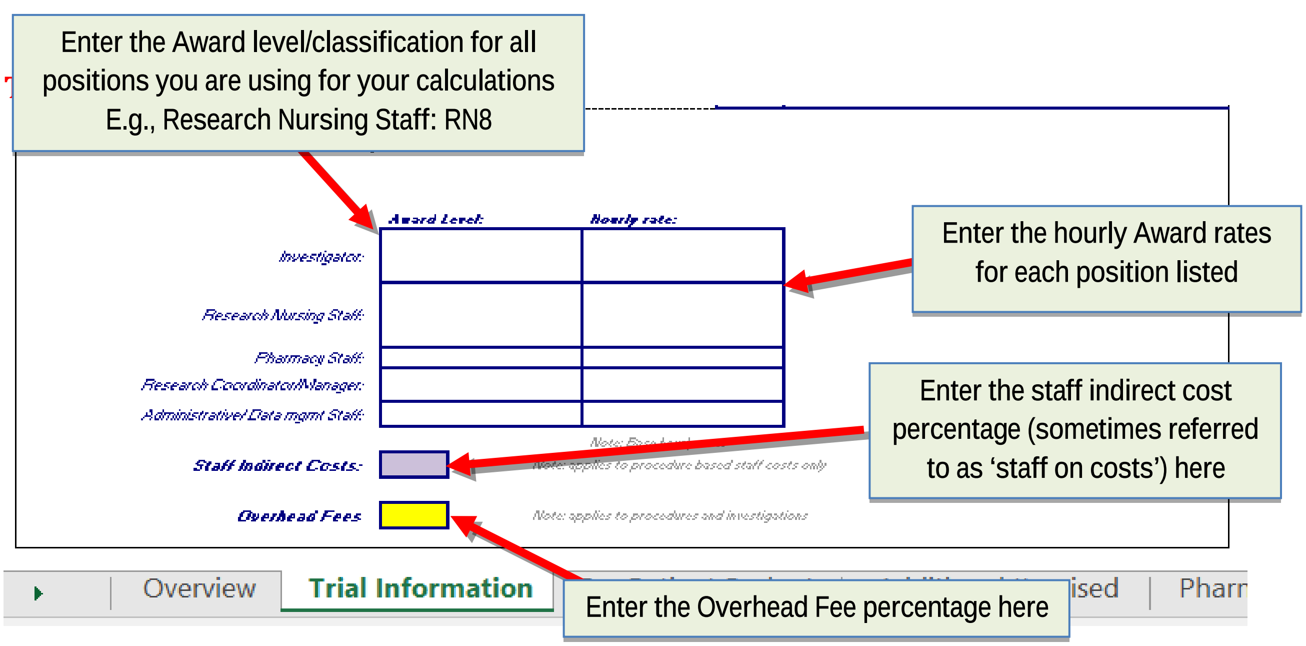
This tab contains instructions on how to navigate and complete the template for your project. You can refer back to this tab at any time for help.



7.2 Trial Information Worksheet

This section requires the input of the study identification information such as study title and protocol/clinical investigational plan number. The information entered here will be used in calculations and to populate text fields throughout the tool.


Trial Information
Please complete below the relevant study information on this tab. The Industry Costing Template will use the information provided in its calculations. Additionally, the sections below will help indicate which sections of this Template that will need to be completed in order to capture the costs associate with your intended study design.
Study Title:
Protocol Number:
Department/Site:
Research Coordinator:
Principal Investigator:
Sponsor:
Funding Body:
HREC:
Estimated Start Date:
Estimated End Date:
Insert study information and contacts. Ensure the version number of the protocol is included
Enter the estimated the number of participants to be enrolled at the site
Total number of patients/participants to be recruited for this study site:
patients/participants
Will the study require the research team to provide assessments and evaluations?
NO
No further action required, please complete all other sections as required
Will the study design require any lab, tests, or scans?
YES
the Per Patient Budget and Set-Up and Other Costs
Is this is a clinical trial of a drug?
NO
The Pharmacy section should be left blank, please complete all other sections as applicable.
Answer these questions to guide completion of the correct worksheets. Select 'Yes' or 'No' from the auto-selection box which appears when the cell is highlighted and follow the instructional text that appears to the right


Enter the Award level/classification for all positions you are using for your calculations E.g., Research Nursing Staff: RN8
Award Level:
Hourly rate:
Investigator:
Research Nursing Staff:
Pharmacy Staff:
Research Coordinator/Manager:
Administrative/ Data mgmt Staff:
Enter the hourly Award rates for each position listed
Staff Indirect Costs:
Note: applies to procedure based staff costs only
Enter the staff indirect cost percentage (sometimes referred to as 'staff on costs') here
Overhead Fees
Note: applies to procedures and investigations
Overview
Trial Information
Enter the Overhead Fee percentage here

7.3 Per-Patient Budget Worksheet

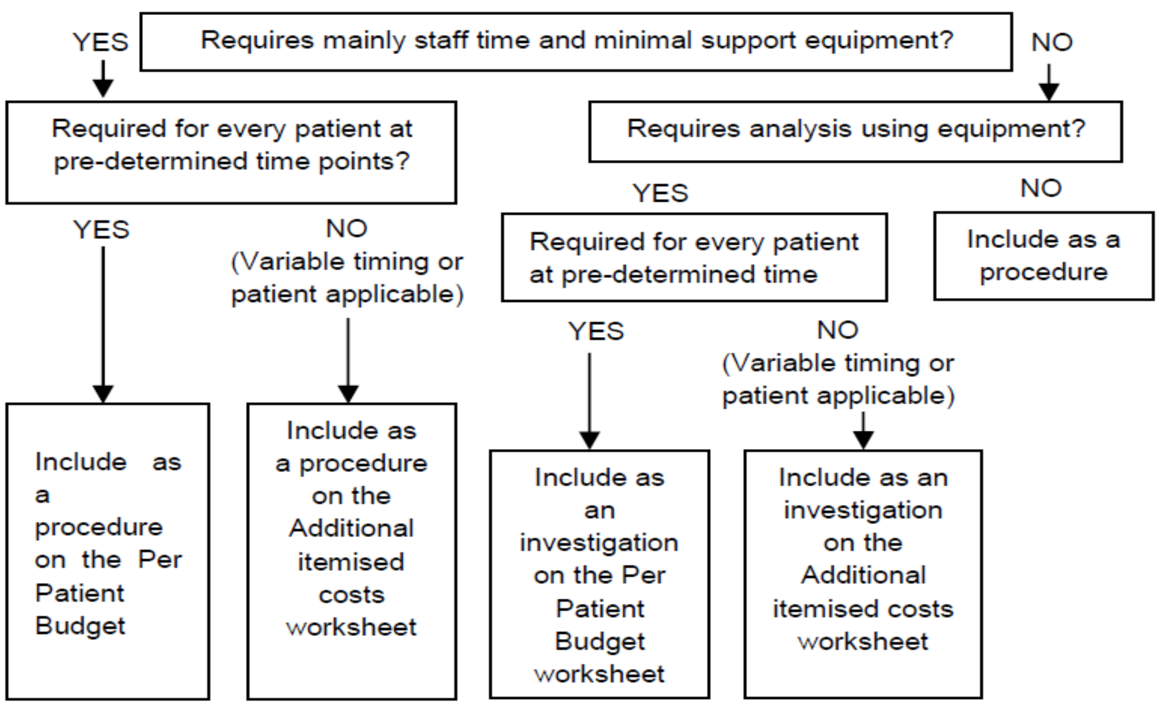
The Per-Patient Budget worksheet requires the identification of all per patient activities conducted within the study, establishing which member of staff would be most likely to perform the activity and the time required to complete each task.

The activities listed in this section should be derived from the Protocol or Clinical Investigational Plan (CIP). The layout allows the list of procedures/investigations to be cross-referenced with the number of times they are performed at each visit, much like a schedule of events table often provided in the protocol.

The Per-Patient Budget worksheet is split into two sections: one for 'procedures' and one for 'investigations', but both use the same method to calculate the costs per patient:

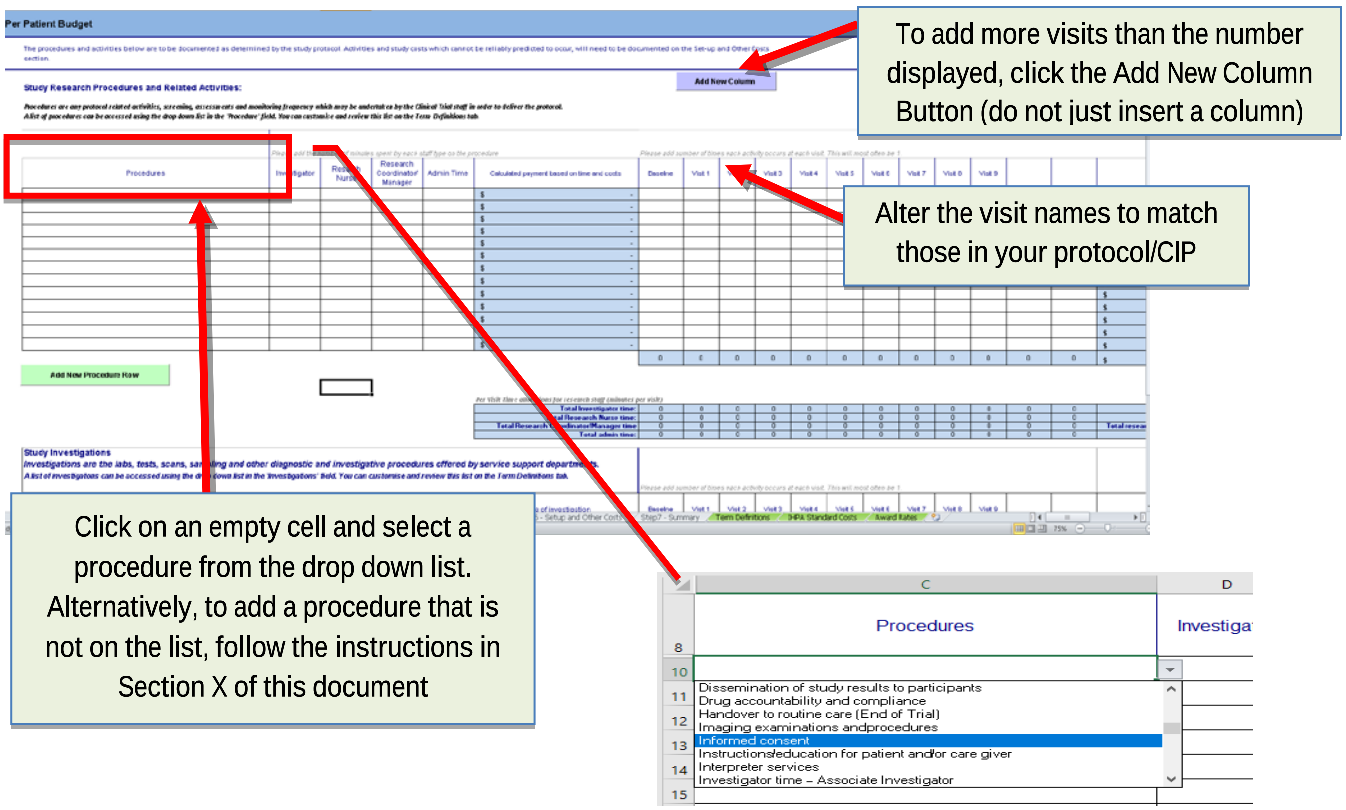
1. Input the activity
2. Assign time (for procedures) or list price (for investigations)
3. Allocate the activity to the correct visits

Determining whether and activity is a procedure or an investigation and which tab to use
Protocol related 'procedures' are undertaken by the clinical trial staff in order to deliver the protocol, whereas 'investigations' (labs, tests, scans, sampling and other diagnostic and investigative activities) are often undertaken within service support departments. The flowchart below can be used to determine if the task is a procedure or an investigation:

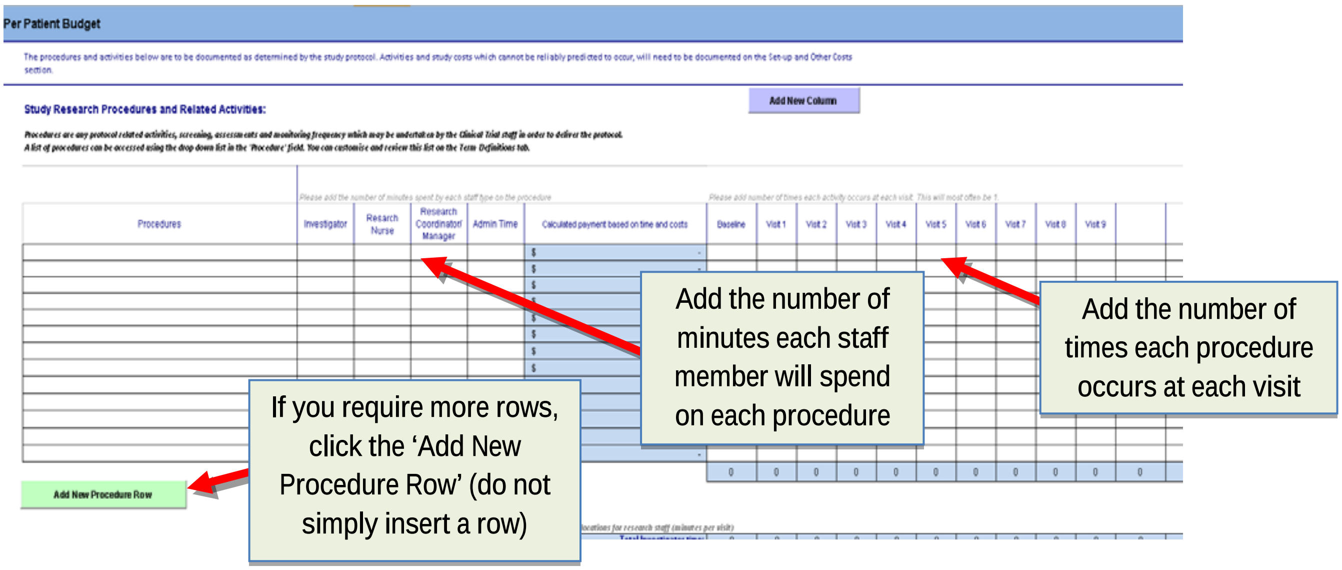


Inputting Procedures

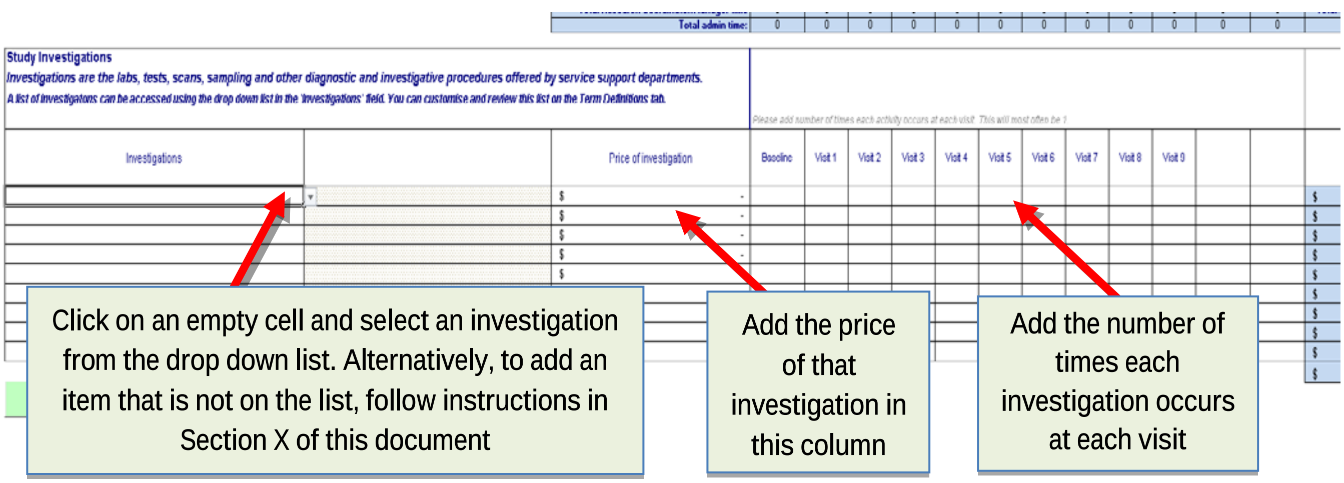
Procedures (including activities or assessments) undertaken by the research team are listed in the first table. Be sure to carefully read the description of each research activity in the Protocol or Clinical Investigational Plan, as many procedures are required to be conducted by specific health care professionals.



Note: It is useful to include procedures in the order they appear in the Protocol/CIP schedule to facilitate review and cross checking. Once you have added a procedure from the drop down list, the rest of the row must be completed as follows:



Inputting Investigations
Investigations are listed in the second table located below the first and work in the same way as the procedures including: adding rows and columns, inserting investigations and adding non-listed procedures. However, the display is slightly different as the costs for investigations already include staff time, therefore the time allocations are not displayed. The process for adding an investigation is similar to that for adding a procedure.

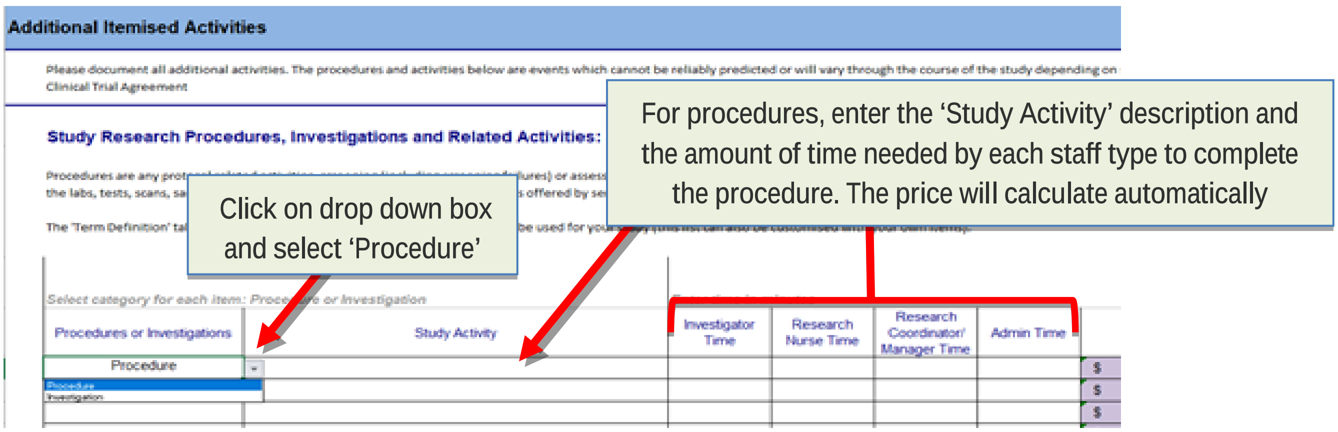


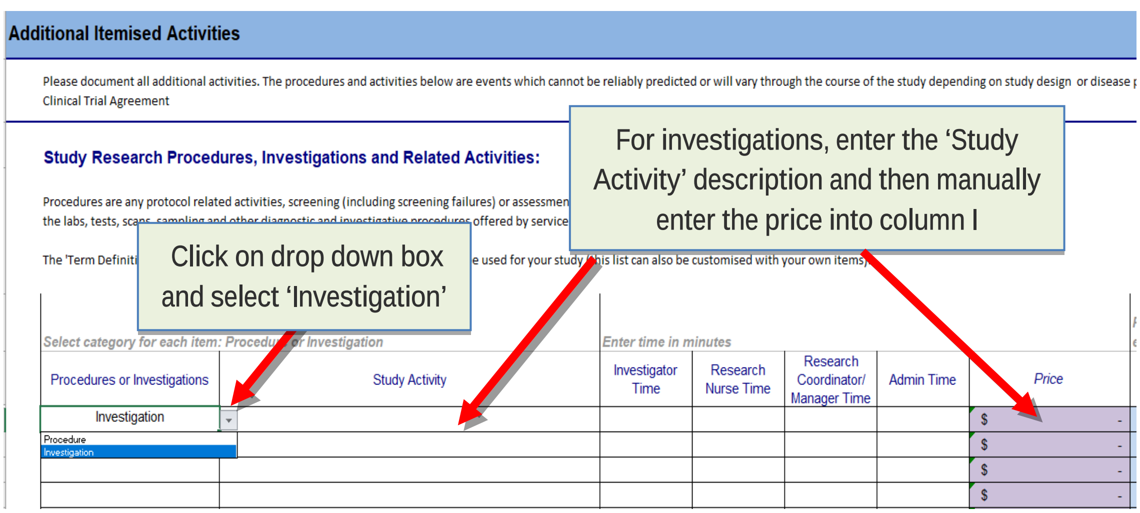
Once completed, the Template will auto-calculate the total cost per visit for both staff activity and Investigations and also the total Per-Patient price.

7.4 Additional Itemised Costs Worksheet

Some costs associated with a clinical trial are not per patient costs (e.g. the review of a new investigator brochure), or are dependent on results of other assessments. These costs can be captured in the Additional Itemised Cost worksheet to agree a price up front, should these assessments be required. This section is also used to capture one off costs, those that will vary throughout the course of the study, or those not always associated with patient visits, for example, budget for a local radio advertisement.

This worksheet uses the same principles as the per patient section. In order for the correct calculation of Staff Indirect Costs and Overhead Fees, either "Procedure' or 'Investigation' must be specified. Once again, for procedures, the cost will be determined by the staff time required and for investigation, a price will be provided. Both are illustrated below:





7.5 Pharmacy Costs Worksheet

This section captures any pharmacy related costs for activities specifically as a requirement of the Clinical Trial i.e. those not normally occurring as part of routine operations for the Pharmacy. Therefore, if an activity is required by the Protocol or Clinical Investigational Plan or is not part of local routine procedures, then the cost needs to be accounted for within the spreadsheet.

There are two tables within this worksheet:

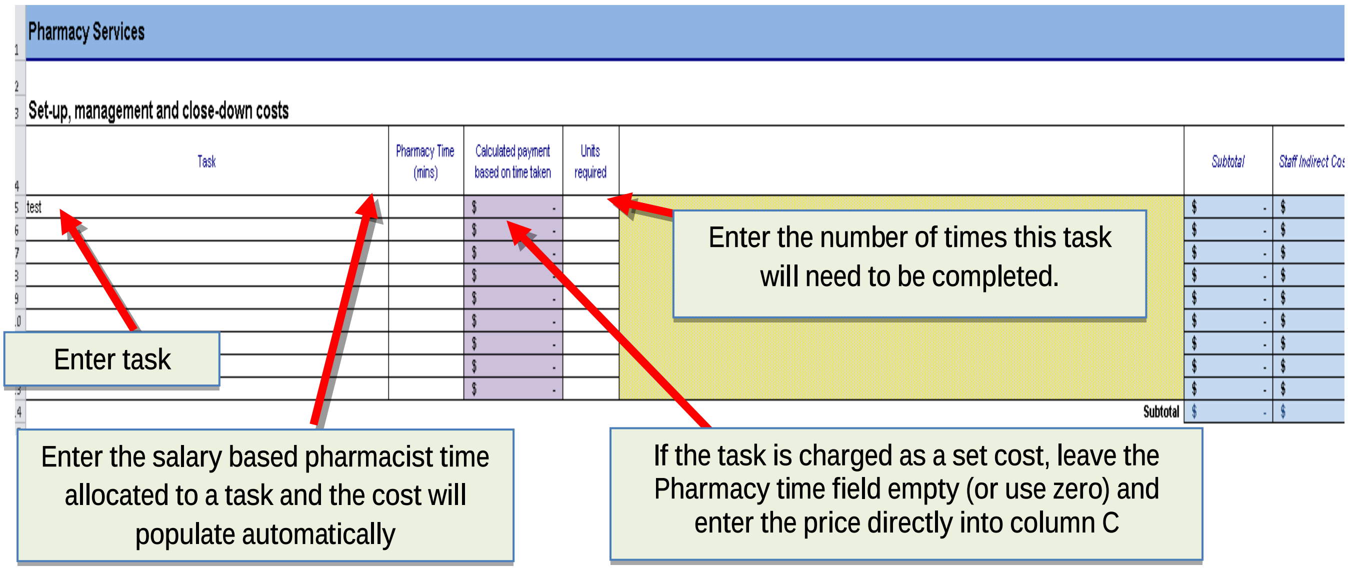
- Pharmacy set-up, management and close-down costs

- Per patient costs (not procedures and investigations)

Pharmacy set-up, management and close-down costs

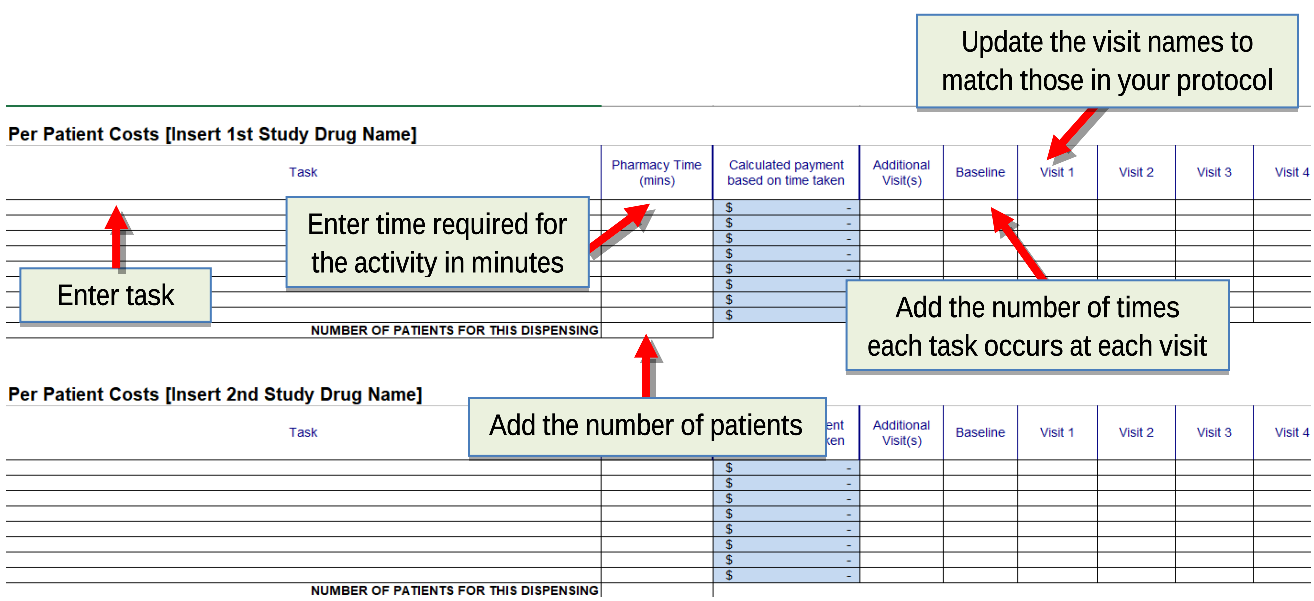
The costs in this table can be calculated in two ways:

- By using a salary-based time allocated to a task (e.g. individual patient drug accountability time, dispensing time)
- By allocating a set cost that is based on the time taken (e.g. waste disposable storage charged as required, out of hours working charged at staff time + 100%)



Per Patient Costs

The per patient sections of the pharmacy worksheet are designed to capture the dispensing related activities for each visit. Multiple study drugs or comparators can be added as required



Once all tables have been completed, the spreadsheet calculates the total pharmacy cost at the bottom of the page.

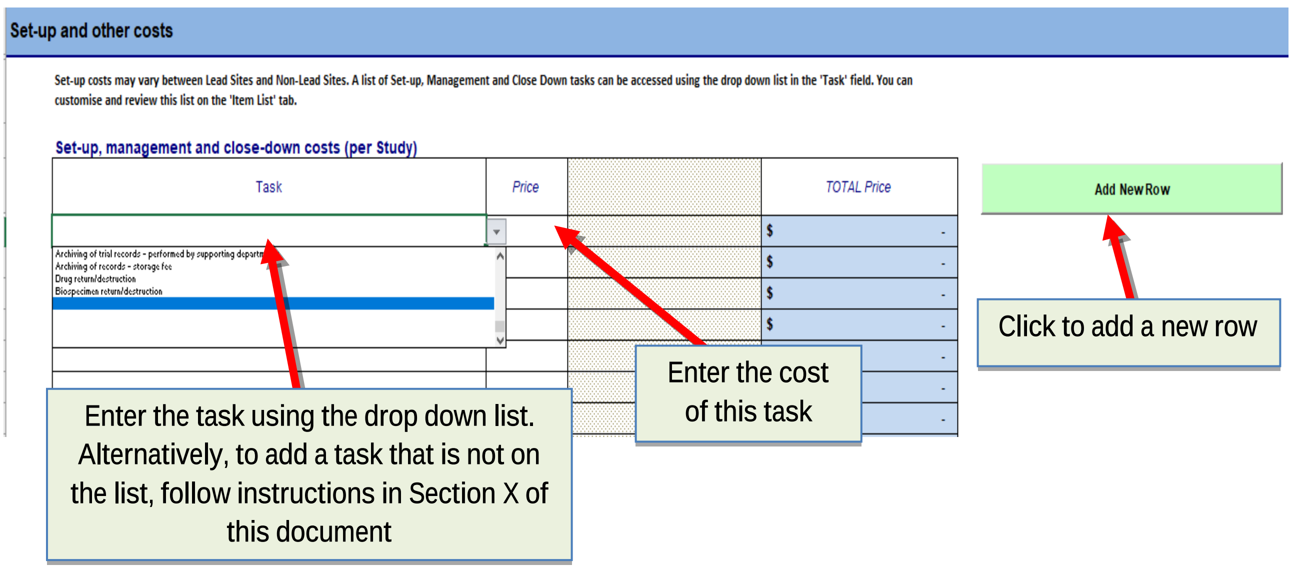
7.6 Set-up and other costs

This worksheet captures all remaining costs associated with conducting a clinical study and is split into two sections.

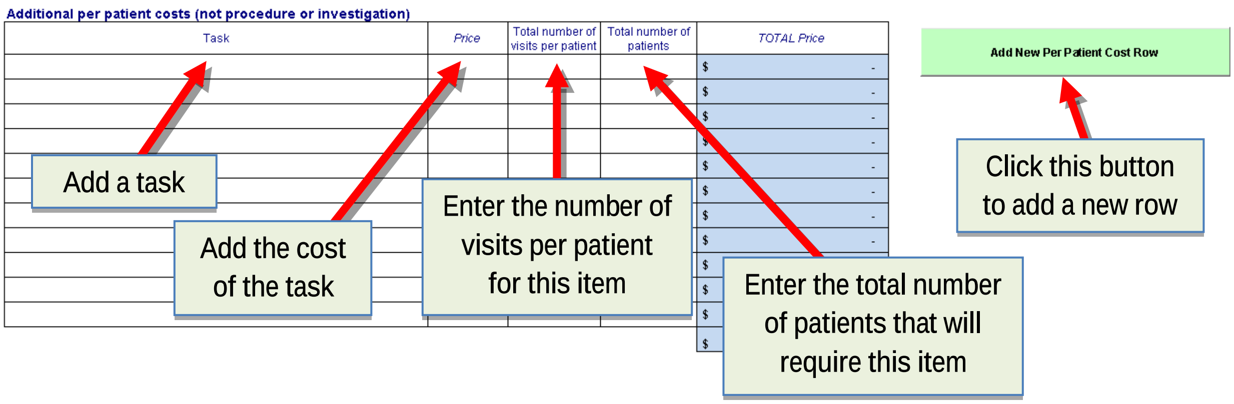
- Set-up, management and close-down fee
- Additional per patient costs (not procedure or investigation)

The template displays a task breakdown associated with study set-up activities to support transparency.

Set-up, management and close-down fee
Set-up costs may vary between Lead Sites and Non-Lead Sites. A list of set-up, management and close down tasks can be accessed using the drop down list in the 'Task' field.



Additional per patient costs (not procedures or investigations)
This table can be used to additional capture patient costs that are based on the number of visits per patient and the total number of patients, <u>but that are not procedures or investigations</u>. Examples include patient or carer refreshments or travel costs, inconvenience payments agreed by the HREC etc.   Further examples can be found in the ‘Item Lists’ tab.

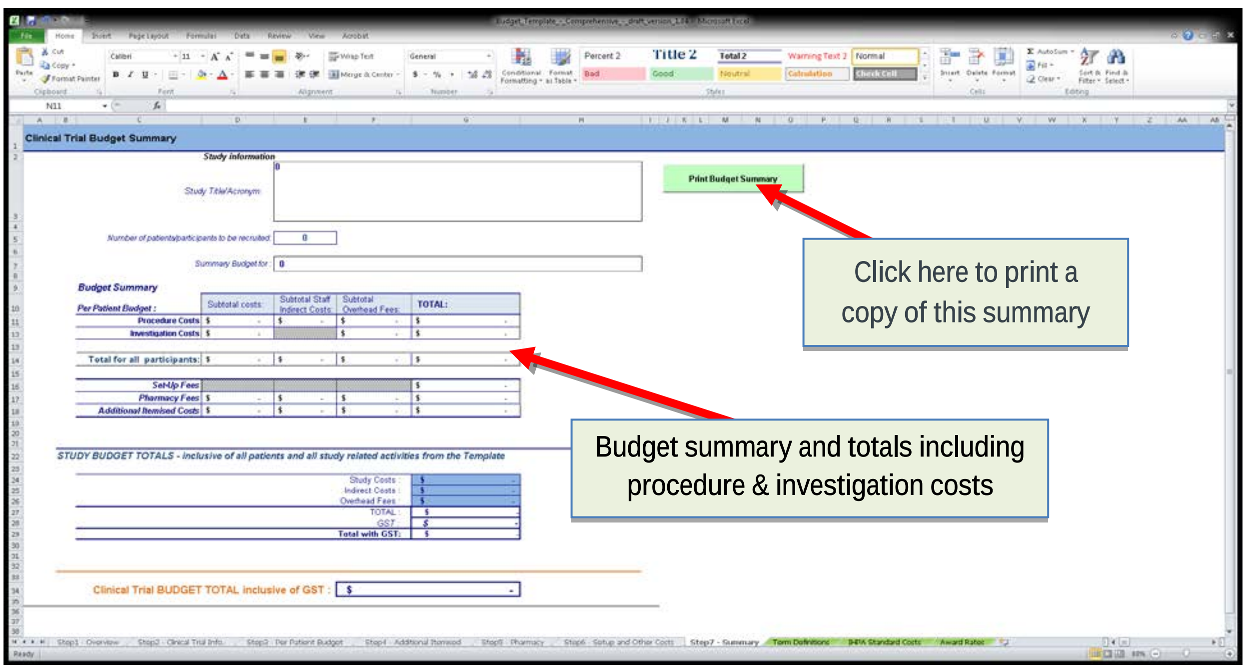

Additional per patient costs (not procedure or investigation)
Task
Price
Total number of visits per patient
Total number of patients
TOTAL Price
Add New Per Patient Cost Row
Add a task
Add the cost of the task
Enter the number of visits per patient for this item
Enter the total number of patients that will require this item
Click this button to add a new row

7.7 Summary Worksheet

This tab automatically displays a summary of all costs entered into all pages in this tool. It shows the sum of:

- Procedural Costs (per patient),
- Investigation Costs (per patient),
- Set-up Fees,
- Pharmacy Fees,
- Additional Itemised Costs (per patient)

For transparency and to enable detailed costing, budgeting and allocation of resources, the costs have been further subdivided into sub total costs.

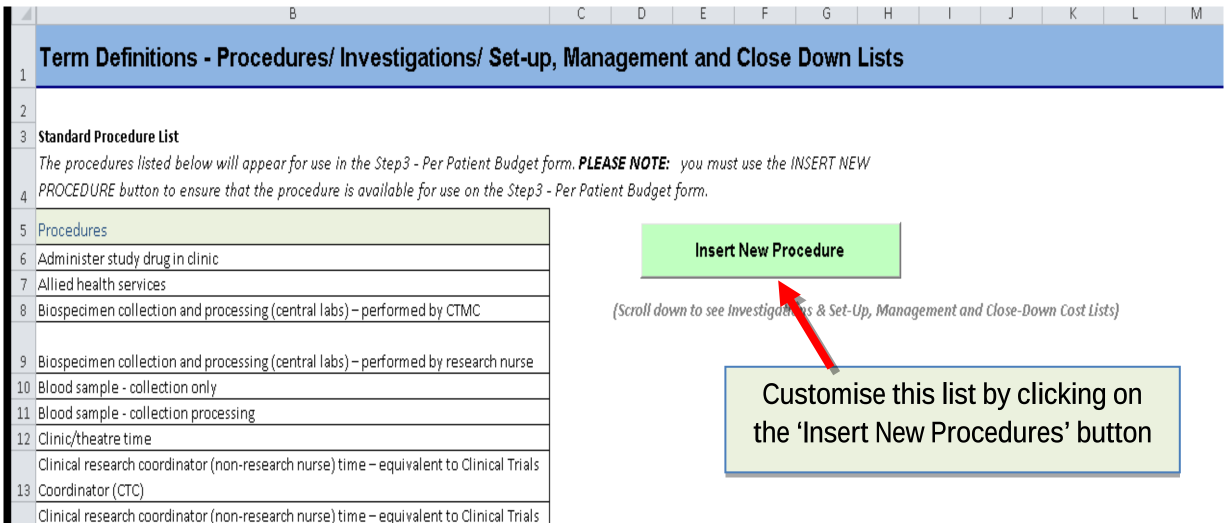


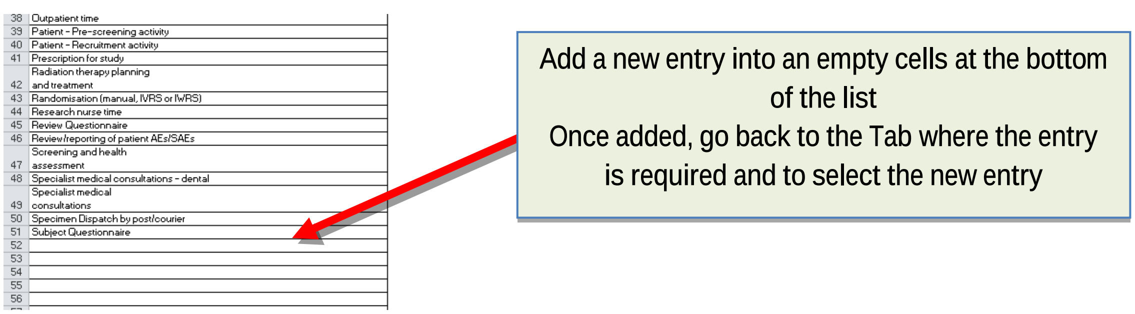
7.8 Item Lists Worksheet

This worksheet includes three tables containing item lists for:

1) Procedures (Per-Patient Budget tab)
2) Investigations (Per-Patient Budget tab)
3) Set-up, Management and Close Down (Set-Up and Other Costs tab)

The lists that are accessed using the drop-down menu items within two worksheets (Per-Patient Budget and Set-Up and Other Costs). If the study requires an entry that isn't included in the dropdown list, <u>it must first be added to the relevant item list by manually inputting the information.</u> Once it has been added it will appear in the drop-down box in the relevant tab and can be selected as normal.





The same procedure should be followed to customise the other tables in this worksheet.

8. Useful links and Resources

Australian Medical Association (AMA): AMA List of Medical Services and Fees - 1 November 2016 (Members Only) https://ama.com.au/resources/fees-list

Independent Hospitals Pricing Authority: Standard List of Clinical Trials Items: covers tests and procedures, clinical trial support services and non-clinical services: https://www.ihpa.gov.au/sites/g/files/net636/f/publications/determination_of_standard_costs_associated_with_clinical_trials_in_australia.pdf

Medicare Benefits Schedule: MBS Online contains the Medicare Benefits Schedule (MBS), a listing of the Medicare services subsidised by the Australian government: http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/downloads

NSW Health Website: Template Clinical Trial Research Agreements & research finance information. http://www.health.nsw.gov.au/ethics/Pages/ctra.aspx >

9. Feedback and Further Development of the Tool

This Tool is version 1 of an ongoing project to streamline the costing process. We would value your feedback to help us continue to develop this tool so that it meets the needs of all stakeholder. You can provide feedback by email to OHMR: E-mail title: COSTING TOOL: researchethics@doh.health.nsw.gov.au

10. Acknowledgements and Working Party

The NSW Costing Template and this User Manual have been based on the work initiated by the UK National Institute of Health Research (NIHR) with kind permission from the NIHR. OHMR gratefully acknowledges the work of the SLHD – Clinical Research Centre, who led the working party that adapted this Tool and User manual for use in Australia.