Independent Hospital Pricing Authority

IHPA

Determination of standard costs associated with conducting clinical trials in Australia

Standard List of Clinical Trial Items

June 2015

Determination of standard costs associated with conducting clinical trials in Australia – Standard List of Clinical Trial Items

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This determination is made by the Independent Hospital Pricing Authority under subsection 131(1) of the National Health Reform Act 2011 (Cth).

Dated 30 June. 2015

Shane Solomon

Mr Shane Solomon
Chair

James Downie
Acting Chief Executive Officer

SEAL OF INDEPENDENT
HOSPITAL PRICING AUTHORITY

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Chapter 1 Overview

On 19 December 2014, the Pricing Authority received a Direction under the *National Health Reform Act* subsection 131(3) from the Commonwealth Minister of Health to determine the costs for the refined list of items and any other items (above those costs required for standard care), as determined necessary by the Pricing Authority, associated with conducting clinical trials in Australia (Direction No. 1 of 2014). The refined list of standard items was determined by the National Health and Medical Research Council (NHMRC).

In determining the costs for the list of standard items, the Pricing Authority has complied with direction in so far as:

(i) In performing the activity described in the Direction, the Pricing Authority must have regard to the matters set out in subsection 131(3) of the Act.

(ii) In addition, the Pricing Authority may, so far as the Act permits, have regard to the following matters:

- (a) The actual activity of each item;
- (b) Principles of cost-recovery; and
- (c) Submissions from relevant parties, including trial sponsors and private hospitals.

In determining the standard costs of these items the Pricing Authority has been assisted by a steering committee including representatives from clinical trial sponsors, hospitals and all Australian governments (with exception of the Northern Territory). A public submission process was also undertaken.

The costs in this Determination relate to the 2014-15 Financial Year. The standard cost for each item includes the allocation of all overheads.

Chapter 2 Explanatory Notes

The costs in Chapter 3 of this Determination were developed through a consultation process involving a wide range of stakeholders. An advisory committee consisting of representatives of trial sponsors, trial collaborative and most jurisdictions provided expert technical input to IHPA throughout this process. A detailed report outlining the process is available on IHPA's website.

In making this Determination, IHPA has utilised the best cost data available at the time, however the data has limitations and in specific trial circumstances the actual cost may be different from the standard cost. As such the standard cost should be regarded as a starting point for discussing the unique features of each proposed trial and the associated costs.

Furthermore, the relevance of each item, and the volumes of each item to be included in each trial budget should also be carefully considered as part of the process of negotiating the trial budget.

The Determination is intended to be applied only to those clinical services that are over and above the normal standard care delivered to patients.

Chapter 3 Table of standard costs for the revised list of items associated with conducting clinical trials in Australia

Sub-List 1 – Site Authorisation

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
Feasibility Assessment	Preliminary assessment	1.1.1	• **$60.38** per *potential* clinical trial	• Based on the assumption that the PI and CTM/C 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 CTM/C (as defined in item 2.6.3). • 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.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Protocol review	1.1.2	• **$407.67** per *potential* clinical trial	• Based on the assumption that the PI and CTM/C 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 CTM/C (as defined in item 2.6.3). • 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.
	Feasibility determination – completion of feasibility questionnaire	1.1.3 (a)	• **$294.62** for completion of feasibility questionnaire required for a *potential* clinical trial	• Based on the assumption that the PI and CTM/C 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 CTM/C (as defined in item 2.6.3). • Standard cost is calculated using the median of the gathered data.
	Feasibility determination – study site visit	1.1.3 (b)	• **$675.95** for study site selection visit required by Sponsor organisation for a *potential* clinical trial	• Based on the assumption that the PI, CTM/C 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 CTM/C (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)). • Standard cost is calculated using the median of the gathered data.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Feasibility determination – budget negotiation and contract review	1.1.3 (c)	• **$755.51** for budget negotiation and contract review for a *potential* clinical trial	• Based on the assumption that the PI, CTM/C, 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 CTM/C (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 $70.59/hour for RGO staff based on the average salary for a research and governance officer is $82,587 plus superannuation). • 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 MTAA 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.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
Ethics Approval	Preparation of the HREC application	1.2.1	• **$2,607.83** per clinical trial (i.e. per HREC application)	• Based on the assumption that the PI and CTM/C 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 CTM/C (as defined in item 2.6.3). • 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.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Ethics review	1.2.2	• **$2,099.42** per clinical trial application	• Based on the assumption that there are eight members on the HREC and the included skill mix are: 1 x chairperson, 1 x legal background; 2 x medical backgrounds, 2 x scientific and/or allied health discipline backgrounds, 1 x ethics officer; 1 x lay members. • 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 not fees incurred.
Site-specific assessment	Preparation of the SSA application by the project team	1.3.1	• **$398.69** per SSA application	• Based on the assumption that the PI and CTM/C are the only two involved in drafting the SSA application 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 CTM/C (as defined in item 2.6.3). In addition, the most common process identified at least three supporting department who will review and sign the SSA, hence up to three supporting department involvement has been factored into the calculation for the standard cost. • Standard cost is calculated using the 25th percentile of the gathered data. • Although it is recognised that the RGO may be involved at this step, all activities (and hence time input) provided by RGO office are captured under item 1.3.2

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Site processing and review	1.3.2	• **$264.71** per SSA application processed	• Based on the assumption that the RGO office is the only personnel/office involved and that the hourly rate (fully absorbed) blended across various positions in the RGO is on an average salary of $82,587 plus superannuation (or $70.59/hour) • Standard cost is calculated using the median of the gathered data. • Across items 1.1.3 and 1.3.2 the estimated RGO time is 5.25 hours per application. • Assumes that the provided Sponsors' contract is either the standard Medicine Australia (MA), or MTAA 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 for this item or item 1.1.3 (c).

Sub-List 2 – Site Implementation

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
Trial initiation	Start-up meetings	2.1.1 (a)	• **$1,879.69** per clinical trial start up meeting (excluding online training)	• Based on the assumption that the mix of staff involved in the start-up meeting (involves organisation of the meeting, a group meeting and one-on-one meetings) includes one PI, two co-PIs, two CTM/C and four staff from supporting departments (e.g. pharmacy, pathology/imaging) attending the group meeting. Although additional staff do often attend (e.g. additional CTC, medical and/or nursing staff etc.) the standard cost reflects the core people identified through the case study visits. • Standard cost is calculated using the 25th percentile of the gathered data. • Excludes any training that needs to be undertaken outside the start-up meeting (e.g. online which is captured under item 2.1.1 (b), (c) and (d).
	Online training undertaken by PI	2.1.1 (b)	• **$282.64** per PI to undertake 1.25 hours of online training per clinical trial	• Based on the assumption that the PI fully absorbed hourly rate is $226.11/hour (as defined in item 2.6.1). • Standard cost is calculated using the 25th percentile of the gathered data.
	Online training undertaken by CTM/C	2.1.1 (c)	• **$295.04** per CTM/C to undertake 3.25 hours of online training per clinical trial	• Based on the assumption that the CTM/C fully absorbed hourly rate is $90.78/hour (as defined in item 2.6.3). • Standard cost is calculated using the 25th percentile of the gathered data.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Online training undertaken by supporting department	2.1.1 (d)	• **$65.04** per supporting department personnel to undertake ¾ hours of online training per clinical trial	• Based on the assumption that the supporting department personnel fully absorbed hourly rate is $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)) • Standard cost is calculated using the 25th percentile of the gathered data. • Only online training undertaken by pharmacy staff that is not drug specific (e.g. GCP etc.) is captured under this item. Drug specific training (e.g. drug preparation, logging etc.) required for any clinical trial undertaken by pharmacy staff is included under item 2.4.1.
	Departmental set up	2.1.2 (a)	• **$1,361.70** per host department per clinical trial	• Based on the assumption that the CTM/C fully absorbed hourly rate is $90.78/hour (as defined in item 2.6.3). • Standard cost is calculated using the 40th percentile of the gathered data as the ERG expressed that the median appeared too high and the 25th percentile too low.
	Departmental set up	2.1.2 (b)	• **$530.40** per pharmacy department per clinical trial	• Based on the assumption that the pharmacist involved in departmental set up has a fully absorbed hourly rate of $88.40/hour (i.e. Grade 3/5 pharmacist). • Standard cost is calculated using the 40th percentile of the gathered data as the ERG expressed that the median appeared too high and the 25th percentile too low.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Departmental set up	2.1.2 (c)	• **$346.88** per other supporting department per clinical trial	• Standard cost is calculated using the 40th percentile of the gathered data as the ERG expressed that the median appeared too high and the 25th percentile too low. • Based on the assumption that the supporting department personnel fully absorbed hourly rate is $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)).
	Trial specific equipment set-up and maintenance	2.1.3	• **$85.04** per piece of trial equipment	• Standard cost is calculated using the median of the gathered data. • Standard costs does not include equipment purchase and/or hire • Standard costs do not include IT personnel time as their involvement was not always required.
Patient accrual	Pre-screening activity	2.2.1	• **$166.15** to screen each potential participant per clinical trial	• Based on the assumption that the PI and CTM/C are the main two involved in pre-screening 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 CTM/C (as defined in item 2.6.3). • Standard cost is calculated using the median of the gathered data.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Recruitment activity	2.2.2	• **$498.45** per potential participant per clinical trial	• Based on the assumption that the PI and CTM/C are the main two involved in recruitment 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 CTM/C (as defined in item 2.6.3). • Standard cost is calculated using the median of the gathered data.
Clinical services	Screening and health assessment	2.3.1	• Calculated per service based on trial protocol using standard costs for items 2.3.2, 2.3.3, 2.3.4, 2.3.5, 2.3.6, 2.3.7 and 2.3.8	• The cost of undertaking a "screening visit and health assessment" is trial protocol dependent and will vary according to the nature of the tests and procedures undertaken and the consultations required with staff involved in the clinical trial. • The cost of undertaking a "screening visit and health assessment" will also vary according to whether components of the screening visits and health assessment are considered standard of care or are in addition to standard of care. • The screening visit and health assessment often includes a range of procedures and/or consultations under items 'clinical services'. All these activities should be costed according to their respective items.
	Laboratory tests and procedures	2.3.2	• 140% of the MBS fee per laboratory test and/or procedure	• The MBS loading reflects the additional reporting requirements required for the clinical trial and/or different procedures (e.g. non-standard parameters for paediatric trials) that need to be followed to meet the protocol requirements. • In some instances, there are tests undertaken locally, for which there is no item listed on the MBS. The costs of these tests should be dealt with under items 2.5.1 – 2.5.4. • Only for non-standard of care laboratory tests and procedures.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Imaging examinations and procedures	2.3.3	• 140% of the MBS fee per imaging examination and/or procedure	• The MBS loading reflects the additional reporting requirements associated with imaging examinations and/or procedures on clinical trial participants. • There are a number of clinical trial specific issues (e.g. imaging examinations in paediatric trials generally take longer and hence are more costly), which may need to be dealt with on a case by case basis with reference to the standard cost. • Not all imaging examinations and/or procedures are included on the MBS (e.g. PET-FLT scans are not currently covered under any MBS item numbers). Where the imaging examinations and/or procedures are not on the MBS then the nearest equivalent imaging examination and/or procedure on the MBS should be used. In the absence of any other data this is considered to be the best approach. • Only for non-standard of care imaging examinations and/or procedures.
	Radiation therapy planning and treatment	2.3.4	• 140% of the MBS fee including ROHPG component per service	• The MBS loading reflects the clinical trial specific activities (e.g. extra reporting, image transfer) associated with radiotherapy services provided to clinical trial participants. • Only for non-standard of care radiation therapy planning and treatment.
	Other clinical tests or procedures	2.3.5	• 140% of the MBS fee per service	• The MBS loading reflects the clinical trial specific activities (e.g. extra reporting, image transfer) provided to clinical trial participants. • Only for non-standard of care other clinical tests or procedures.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Specialist medical consultations	2.3.6 (a)	• 140% of the MBS fee per specialist medical (including GP) service	• The MBS loading reflects the clinical trial specific activities (e.g. extra reporting, extra information) provided to clinical trial participants. • Only for non-standard of care specialist medical consultations.
	Specialist medical consultations - dental	2.3.6 (b)	• 100% of ADA fee per specialist dental service	• The ADA Fee is unadjusted because it allows for a return on investment component in setting the fee. • Only for non-standard of care specialist medical consultations.
	Nursing services	2.3.7	• **$81.90** per nurse consultation (based on 140% of the identified MBS fees)	• The MBS loading reflects the trial specific activities (e.g. extra reporting, extra information) provided to clinical trial participants. • Only for non-standard of care nursing services.
	Allied health services	2.3.8	• **$98** per allied health consultation (based on 140% of the identified MBS fees)	• The MBS loading reflects the trial specific activities (e.g. extra reporting, extra information) provided to clinical trial participants. • Only for non-standard of care allied health services.
Pharmacy / Investigation Drug Related	Staff training (drug specific)	2.4.1	• **$176.80** per pharmacist to undertake two hours of drug specific training per clinical trial	• Based on the assumption that the pharmacist involved has a fully absorbed hourly rate of $88.40/hour (i.e. Grade 3/5 pharmacist)) and that the training takes two hours per pharmacist. • Standard cost is calculated using the 25th percentile of the gathered data. • Charged by pharmacy department only and is for drug specific training only. Other online training related to the clinical trial is captured under item 2.1.1 (d).

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Stock management – drug stock received	2.4.2 (a)	• **$72.85** per drug stock received	• Based on the assumption that stock management involves a pharmacy technician overseen by a pharmacist at a fully absorbed hourly rate of $88.40 (pharmacist) and $57.30 (for the pharmacy technician which is assumed to have a salary equivalent to a Grade 1 pharmacist) • Task is undertaken per stock delivery received • Standard cost is calculated using the 25th percentile of the gathered data.
	Stock management – expiry management	2.4.2 (b)	• **$9.17** for expiry management per week	• Based on the assumption that expiry management is done weekly by a pharmacy technician at a fully absorbed hourly rate of $57.30 (assumed to have a salary equivalent to a Grade 1 pharmacist) • Standard cost is calculated using the 25th percentile of the gathered data.
	Drug preparation and dispensing – drug manufacturing	2.4.3 (a)	• **$169.43** for drug manufacturing (if required)	• Based on the assumption that two pharmacists are required to manufacture any clinical trials drugs at a fully absorbed hourly rate of $88.40 (i.e. Grade 3/5 pharmacist as defined under item 2.6.3). • Most of the drug manufacturing was found not to be done by clinical trial sites involved in the study. Where it was found to be done at participating sites, there was wide variation in time spent on manufacturing the required clinical trials drugs. • The cost associated with drug manufacturing may need to be negotiated on a per trial basis with some reference to this standard cost. • Standard cost is calculated using the median of the gathered data.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Drug preparation and dispensing – simple	2.4.3 (b)	• **$43.32** for simple clinical trial drug preparation and dispensing	• Based on the assumption that two pharmacists are required to undertake simple (based on volume of items and complexity of process e.g. counting tablets, measuring liquids etc.) preparation and dispensing clinical trials drug activities at a fully absorbed hourly rate of $88.40 (i.e. Grade 3/5 pharmacist as defined under item 2.6.3). • Developing a standard cost for simple drug preparation and dispensing activities was difficult due to the wide variation which is dependent on the type and number of drugs involved in the trial. • Clinical trial budgets may need to be negotiated on a per trial basis with reference to the standard cost. • Standard cost is calculated using the median of the gathered data.
	Drug preparation and dispensing – complex	2.4.3 (c)	• **$110.21** for complex clinical trial drug preparation and dispensing	• Based on the assumption that two pharmacists are required to undertake complex (based on volume of items and complexity of process e.g. aseptic or cytotoxic) preparation and dispensing clinical trials drug activities at a fully absorbed hourly rate of $88.40 (i.e. Grade 3/5 pharmacist as defined under item 2.6.3). • Developing a standard cost for complex drug preparation and dispensing activities was difficult due to the wide variation which is dependent on the type and number of drugs involved in the trial. • Clinical trial budgets may need to be negotiated on a per trial basis with reference to the standard cost. • Standard cost is calculated using the median of the gathered data.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Drug preparation and dispensing – drug accountability	2.4.3 (d)	• **$14.33** for clinical trial drug accountability activities per clinical trial participant	• Based on the assumption that drug accountability activities is largely undertaken by a pharmacy technician at a fully absorbed hourly rate of $57.30 (assumed to have a salary equivalent to a Grade 1 pharmacist). • Standard cost is calculated using the median of the gathered data.
	Drug preparation and dispensing – provision of counselling	2.4.3 (e)	• **$18.12** for provision of counselling services by a pharmacist at the time of dispensing the clinical trial drug(s) to a clinical trial participant	• It was found that counselling is not also performed by the pharmacy department (sometimes CTM/C takes on this role), however when it does this standard cost is based on the assumption that a pharmacist is required at a fully absorbed hourly rate of $88.40 (i.e. Grade 3/5 pharmacist as defined under item 2.6.3). • Standard cost is calculated using the median of the gathered data.
Biospecimen related	Biospecimen collection and processing (central labs) – performed by research nurse	2.5.1 (a)	• **$28.05** per clinical trial participant as per the occurrences described in the clinical trial protocol	• Based on the assumption that the biospecimen collection and processing is undertaken by a research nurse at a fully absorbed hourly rate of $74.79 as defined under item 2.6.2. • Standard cost does not include the transport costs (e.g. courier costs, any required quarantine permits, etc.) as these costs varied depending on the amount of biospecimens being transported, the delivery location (e.g. within Australia or overseas) as well as the temperature at which the biospecimens need to be transported. • Standard cost is calculated using the median of the gathered data.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Biospecimen collection and processing (central labs) – performed by research nurse	2.5.1 (b)	• **$34.04** per clinical trial participant as per the occurrences described in the clinical trial protocol	• Based on the assumption that the biospecimen collection and processing is undertaken by the CTM/C at a fully absorbed hourly rate of $90.78 as defined under item 2.6.3. • Standard cost does not include the transport costs (e.g. courier costs, any required quarantine permits, etc.) as these costs varied depending on the amount of biospecimens being transported, the delivery location (e.g. within Australia or overseas) as well as the temperature at which the biospecimens need to be transported. • Standard cost is calculated using the median of the gathered data.
	Biospecimen collection and processing (central labs) – performed by pathology staff personnel	2.5.1 (c)	• **$31.89** per clinical trial participant as per the occurrences described in the clinical trial protocol	• Based on the assumption that the biospecimen collection and processing is undertaken by pathology department personnel (i.e. hospital scientist Grade 3/4) at a fully absorbed hourly rate of $85.04. • Standard cost does not include the transport costs (e.g. courier costs, any required quarantine permits, etc.) as these costs varied depending on the amount of biospecimens being transported, the delivery location (e.g. within Australia or overseas) as well as the temperature at which the biospecimens need to be transported. • Standard cost is calculated using the median of the gathered data.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Biospecimen storage	2.5.2	• Included under item 2.5.1 where the collection and processing of a biospecimen attracts an MBS fee • Where the collection and processing of a biospecimen does not attract an MBS biospecimen storage costs should be covered by the nearest equivalent MBS item	• Study found that the majority of biospecimens are not stored at local hospitals for prolonged periods of time. Generally they are regularly sent to the sponsor throughout the life of a trial, or at the end of the trial. Where specimens were found to be stored on site, they were generally small amounts and did not consume significant space.
Clinical resources	Investigator time – Principal investigator	2.6.1 (a)	• **$226.11** per hour for principal investigator	• Based on the assumption that the PI is a senior specialist (i.e. average between years 8 and 9 on the AMA rates was used). • This item should only be used where the clinician is acting in his/her capacity as an investigator and should not include items costed on a per service basis (i.e. items under clinical services).
	Investigator time – sub/co-investigator	2.6.1 (b)	• **$199.11** per hour for sub/co-investigator	• Based on the assumption that the sub/co-PI is less experienced than the PI but still a senior specialist (i.e. years 5 on the AMA rates was used). • This item should only be used where the clinician is acting in his/her capacity as an sub/co-investigator and should not include items costed on a per service basis (i.e. items under clinical services).

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Research nurse time	2.6.2	• **$74.79** per hour for research nurse	• Based on the assumption that the research nurse is a clinical nurse specialist (CNS), taken at the average of a year 1 and 2 CNS. • This item should only be used where the clinician is acting in his/her capacity as an research nurse and should not include items costed on a per service basis (i.e. items under clinical services).
	Clinical research coordinator (non-research nurse) time – equivalent to Clinical Trials Coordinator (CTC)	2.6.3 (a)	• **$82.74** per hour for clinical research coordinator (equivalent to CTC)	• This role is more commonly known as a clinical trials coordinator (CTC) and the discipline filling the positions varied between those qualified as registered nurses or those with scientific qualifications (e.g. Grade 3/4 scientist) and/or allied health qualifications (e.g. pharmacist (e.g. Grade 3/5 pharmacist)). • Based on the assumption that the position of CTC is filled equally by a mix of the above identified disciplines. • This item should only be used where the position is acting in his/her capacity as a CTC and should not include items costed on a per service basis (i.e. items under clinical services).

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Clinical research coordinator (non-research nurse) time – equivalent to Clinical Trials Manager (CTM)	2.6.3 (b)	• **$93.16** per hour for clinical trials manager (CTM)	• The role of the CTM is to coordinate CTCs and is often heavily involved in the site authorisation process (more so than the CTC where the role of CTM exists). The CTM is usually a senior nurse, whose prior position was either a NUM or more commonly a CNC. • Based on the assumption that the position of CTM is filled equally by a CNC Grade 3. • This item should only be used where the position is acting in his/her capacity as a CTM and should not include items costed on a per service basis (i.e. items under clinical services).
	Clinical research coordinator (non-research nurse) time – equivalent to Clinical Trials Manager (CTM)/Clinical Trials Coordinator (CTC)	2.6.3 (c)	• **$90.78** per hour for CTM/CTC	• A blended CTM/C hourly rate was calculated as the existence of either or both positions within hospital departments varies. • This item should only be used where the position is acting in his/her capacity as a CTM/C and should not include items costed on a per service basis (i.e. items under clinical services).
	Interpreter services	2.6.4	• **$53.91** per hour	• Found to be rarely used, although when used some sites use contracted interpreter services whereas other sites had interpreters (for at least the most common languages) available on site.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Ward bed days	2.6.5	• **$1,130** per day	• A cost per ward bed days was calculated using NHCDC data from 2012-13. Excludes the cost components: allied health (as captured under item 2.3.8) imaging (as captured under item 2.3.3), pathology (as captured under item 2.3.2) and theatre costs (as captured under item 2.6.6). • The 2012-13 costs have been indexed as per the National Efficient Price Determination for 2013-14 indexation rate. • The costs calculated have been based on are the national costs, inclusive of all states/territories.
	Clinic/theatre time	2.6.6	• **$980** per theatre/clinic hour (excluding medical costs)	• The standard cost excludes medical costs (as these cost elements have been identified elsewhere (e.g. items 2.3.6 and 2.6.1). • Data were provided on hospitals in Queensland, South Australia and New South Wales. • Standard cost is calculated using the median of the gathered data.
	Outpatient time	2.6.7	• Not calculated	• Through both consultations with sites and through the public consultation process, majority view was that this item appeared to duplicate other items in the list (e.g. mainly items 2.3.6, 2.3.7 and 2.3.8). We are therefore suggesting that this item be deleted from the revised list.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
Trial operation	Lead site coordination – four or less sites	2.7.1 (a)	• **$2,436.81** per clinical trial per annum	• Based on the assumption that the PI and CTM/C are the only two involved in lead site coordination 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 CTM/C (as defined in item 2.6.3). • Standard cost is calculated using the 25th percentile of the gathered data.
	Lead site coordination – more than four sites	2.7.1 (b)	• **$5,100.08** per clinical trial per annum	• Based on the assumption that the PI and CTM/C are the only two involved in lead site coordination 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 CTM/C (as defined in item 2.6.3). • Standard cost is calculated using the median of the gathered data.
	Administration, monitoring and reporting – administration activities	2.7.2 (a)	• **$1,073.32** per clinical trial per annum for administration activities	• Administration activities include tasks that occur post the establishment phase, including managing clinical trial documentation; retrieving medical and/or clinical records; invoicing; organising and maintaining virtual private network (VPN) access; and liaison with investigators and/or sponsor. • Standard cost is calculated using the median of the gathered data.
	Administration, monitoring and reporting – eCRF or CRF completion	2.7.2 (b)	• **$45.39** per eCRF or CRF per participant per visit	• Standard cost is calculated using the 25th percentile of the gathered data.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Administration, monitoring and reporting – monitor visits	2.7.2 (c)	• **$234.03** per monitor visit (including remote monitoring visits)	• Standard cost is calculated using the 25th percentile of the gathered data.
	Administration, monitoring and reporting – review of line items/SAE reports	2.7.2 (d)	• **$77.23** per review of line listing/SAE reports	• Standard cost is calculated using the 25th percentile of the gathered data.
	Administration, monitoring and reporting – other annual reporting	2.7.2 (e)	• **$745.65** per clinical trial per annum for reporting activities – other annual reporting	• Other annual reporting includes tasks accrual reporting; an annual governance reporting and annual ethic report but excludes safety and adverse/incident event reporting which is captured under item 2.7.2 (f). • Standard cost is calculated using the median of the gathered data.
	Administration, monitoring and reporting – preparation of SAE and/or incident reports	2.7.2 (f)	• **$251.69** per SAE and/or incident report prepared	• Standard cost is calculated using the 25th percentile of the gathered data.
Participant related	Participant time	2.8.1	• **$49.19** per hour	• Based on the average of a range of identified consumer hourly rates available in the public domain for similar activities.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Participant costs - accommodation	2.8.2 (a)	• **$183** per night for accommodation	• Based on the average of the rate for overnight accommodation in the capital cities, as published on the ATO website, has been used to calculate the standard cost.
	Participant costs – breakfast	2.8.2 (b)	• **$25.35** per breakfast meal	• The calculated standard cost is based on the generic rate (i.e. no variation based on location) published on the ATO website, for those on an annual salary less than $112,610.
	Participant costs – lunch	2.8.2 (c)	• **$28.55** per lunch meal	• The calculated standard cost is based on the generic rate (i.e. no variation based on location) published on the ATO website, for those on an annual salary less than $112,610.
	Participant costs – dinner	2.8.2 (d)	• **$48.65** per dinner meal	• The calculated standard cost is based on the generic rate (i.e. no variation based on location) published on the ATO website, for those on an annual salary less than $112,610.
	Participant costs – car per km	2.8.2 (e)	• Car travel per km by car type	• The calculated standard cost is based on the rates per km by car type published on the ATO website.
	Participant costs – car parking		• Car parking – at cost incurred	• Car parking varies greatly dependent on location and the length of the clinical trial specific visit. As such it is suggested that car parking is reimbursed (by receipt) at the cost that has been incurred.
Amendment Processing	Amendment preparation and submission – minor amendment	2.9.1 (a)	• **$128.47** per minor amendment	• Based on the assumption that the PI and CTM/C are the only two involved in preparing minor amendments 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 CTM/C (as defined in item 2.6.3). • Standard cost is calculated using the 25th percentile of the gathered data.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Amendment preparation and submission – major amendment	2.9.1 (b)	• **$238.09** per major amendment	• Based on the assumption that the PI and CTM/C are the only two involved in preparing major amendments 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 CTM/C (as defined in item 2.6.3). • Standard cost is calculated using the median of the gathered data.
	Amendment preparation and submission – if re-consenting required	2.9.1 (c)	• **$113.06** per participant if re-consenting is required as a result of the amendment	• Based on the assumption that if re-consenting is required as a result of a major amendment then this will be undertaken by the PI at the hourly rate (fully absorbed) of $226.11/hour (as defined in item 2.6.1). • Standard cost is calculated using the median of the gathered data.
	Amendment review – minor amendment by HREC office	2.9.2 (a)	• **$35.30** per minor amendment/SAE review by HREC office	• Based on the assumption that review/processing of a minor amendment or minor SAE involves the HREC officer only at an assumed fully absorbed hourly rate of $70.59 based on an assumed average annual salary of $82,587 plus superannuation. • Standard cost is calculated using the median of the gathered data.
	Amendment review – major amendment by HREC office	2.9.2 (b)	• **$238.81** per major amendment/SAE review by HREC office (including it being tabled at HREC meeting)	• Based on the assumption that a major amendment/SAE will be prepared and presented at a HREC meeting involving the same eight people identified in item 1.2.2. • Standard cost is calculated using the median of the gathered data.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Amendment review – if re-consenting required by RGO office	2.9.2 (c)	• **$35.30** per minor amendment/SAE review by RGO	• Based on the assumption that review/processing of a minor amendment or minor SAE submitted to the RGO involves the RGO officer only at an assumed fully absorbed hourly rate of $70.59 based on an assumed average annual salary of $82,587 plus superannuation. • Standard cost is calculated using the median of the gathered data.

Sub-List 3 – Site Closeout

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
Site closeout visit	Site closeout visit	3.1.1	• **$821.26** per clinical trial	• Based on the site closeout visit activities including the CTM/C (fully absorbed hourly rate of $90.78 as defined under item 2.6.3), PI (fully absorbed hourly rate of $226.11 as defined under item 2.6.1) and personnel from involved supporting departments (fully absorbed hourly rate of $86.72 (i.e. blend of a hospital scientist (i.e. Grade 3/4 hospital scientist) and pharmacist (i.e. Grade 3/5 pharmacist). • Standard cost is calculated using the median of the gathered data.
Record archiving	Archiving of trial records – performed by host department	3.2.1 (a)	• **$272.34** per clinical trial	• Based on the assumption that the CTM/C is the only person involved in archiving of trial records of the host department at an hourly rate (fully absorbed) of $90.78/hour (as defined in item 2.6.3). • Standard cost is calculated using the median of the gathered data.
	Archiving of trial records – performed by supporting departments	3.2.1 (b)	• **$86.72** per clinical trial	• Based on the assumption that one person within each supporting department will be designated to perform the archiving of trial records in their department at a blended hourly rate (fully absorbed) of $86.72/hour (i.e. blend of a hospital scientist (i.e. Grade 3/4 hospital scientist) and pharmacist (i.e. Grade 3/5 pharmacist). • Standard cost is calculated using the median of the gathered data.

Major category	Item	Reference number	Standard cost	Comments to guide use of the standard cost
	Archiving of trial records – storage fee	3.2.1 (c)	• $1,575.00 per clinical trial	• Based on the assumption that the storage fee charged to the hospital department is $30.00 per box and that on average 3.5 boxes are stored for 15 years. • Standard cost is calculated using the median of the gathered data.
Drug return/destruction	Drug return/destruction	3.3.1	• **$72.24** per drug return/destruction process	• Based on the assumption that drug return/destruction activities is largely undertaken by a pharmacy technician at a fully absorbed hourly rate of $57.30 (assumed to have a salary equivalent to a Grade 1 pharmacist) but overseen by a pharmacist (average fully absorbed hourly rate of $88.40 for Grade 3/5 pharmacist (as defined in 2.6.3). • Drug return/destruction occurs throughout the trial not just at close out. • Standard cost assumes that the accountability, boxing up and returning excess stock to the Sponsor is undertaken by hospital staff (i.e. pharmacy technician and/or pharmacist) and not the Sponsor (during a monitoring visit) • Standard cost is calculated using the median of the gathered data.
Biospecimen transfer/destruction	Biospecimen return/destruction	3.4.1	• **$85.04** per biospecimen return/destruction process	• The loading associated with item 2.3.2 already incorporates destruction of biospecimens for those biospecimens covered under the MBS. Hence item 3.4.1 is only relevant for biospecimen return and/or destruction not included under the MBS. • Standard cost is calculated using the median of the gathered data.