Orygen
The National Centre of Excellence in Youth Mental Health

Policy Submission

Standard Costs for Conducting Clinical Trials in Australia

1. About this submission

This submission is made on behalf of Orygen – The National Centre of Excellence in Youth Mental Health in response to the Independent Hospital Pricing Authority's Development of a Table of Standard Costs for Conducting Clinical Trials in Australia public consultation paper. The main purpose of this submission is to identify items included in the consultation paper that may impact on research activity relating to the mental health of young people aged 12-25.

2. About Orygen – The National Centre for Youth Mental Health

Who we are

Orygen, The National Centre of Excellence in Youth Mental Health is the world's leading research and knowledge translation organisation focusing on mental ill-health in young people.

At Orygen, our leadership and staff work to deliver cutting-edge research, policy development, innovative clinical services, and evidence-based training and education to ensure that there is continuous improvement in the treatments and care provided to young people experiencing mental ill-health.

Our work has created a new, more positive approach to the prevention and treatment of mental disorders, and has developed new models of care for young people with emerging disorders. This work has been translated into a worldwide

shift in services and treatments to include a primary focus on getting well and staying well, and health care models that include partnership with young people and families.

Orygen conducts clinical research, runs clinical services (four headspace centres), supports the professional development of the youth mental health workforce and provides policy advice to the Commonwealth Government relating to young people's mental health.

Orygen's current research strengths include early psychosis, personality disorders, functional recovery and neurobiology. Other areas of notable research activity include emerging mental disorders, mood disorders, online interventions and suicide prevention. Orygen supports its clinical research with a developing health economic and health services research programme that spans the range of its research activities.

Orygen has been tasked by the Australian Government to produce a National Youth Mental Health Research Priorities and Implementation Framework.

Our governance

Orygen, The National Centre of Excellence in Youth Mental Health is a not-for-profit company limited by guarantee, a charitable entity with Deductible Gift Recipient Status and an approved research institute. The Company has three Members: the Colonial Foundation, The University of Melbourne and Melbourne Health.

Orygen is led by a Board of Directors, which is chaired by Mr Peter Smedley. The Board's operations are informed and supported by an Audit and Risk Committee and a Scientific Advisory Committee.

Executive Director Professor Patrick McGorry AO leads the Executive, which is responsible for delivering Orygen's Strategic Plan and managing all aspects of the organisation's daily operations.

Sponsor Operations

Orygen is the study 'Sponsor' for the majority of our clinical research studies. The role of Sponsor means Orygen holds overall responsibility for the management and oversight of clinical research activities conducted at our investigator sites (locally, nationally and internationally). This responsibility also includes governance and quality assurance activities.

Part of Orygen's Sponsor responsibilities includes compliance oversight and independent monitoring of our studies – in simple terms this means ensuring that studies are enacted according to their protocols, relevant legislation/guidelines, and appropriate mechanisms are used to ensure and manage participant safety and well-being. Sponsor Operations enables this critical role and provides insight into the conduct and costing of investigator-initiated and commercially sponsored clinical trials in the challenging and complex mental health research environment.

Sponsor Operations also facilitates service level and collaborative agreements with our many partners to ensure accountabilities and expenditure on clinical research projects are adequately considered. Their objective is to foster engagement with staff and study teams, which includes good planning at the outset of all Orygen sponsored clinical research studies.

3. Key recommendation

Orygen supports the overall goal of developing a table of standard costs relevant to current practice that can usefully inform trial budget negotiations between research funders/sponsors and health services hosting research activity.

To ensure that the development of the table of standard costs adequately accounts for some of the specific needs of the mental health research domain, our key recommendation is that the IHPA proactively engages relevant stakeholders in mental health services and research (including but not limited to service providers and researchers focused on the mental health of young people) in the next phase of this consultation.

We note that the consultation paper states that targeted interviews and focus groups are currently planned and ongoing as part of the consultation process, so recommend that part of this activity be specifically directed to eliciting the views and experiences of stakeholders concerned with youth mental health research.

We believe that such a proactive outreach effort is important because:

- There is a wide diversity in the types of settings in which clinical trials in mental health occur, thus increasing the potential for some standard cost items to inadequately capture what may be common practices in mental health research.

- In the youth mental health domain, there is an ongoing effort to develop a new youth mental health service system stream (through initiatives like headspace, the youth early psychosis program and e-headspace) along with other youth specific streams of care in the private, public and NGO sectors. The environment and institutional support for research in these emerging clinical platforms is quite distinctive from that in traditional healthcare settings (such as hospitals) and we would anticipate that this would affect the cost base for a number of research activities.
- Likely due to the general underfunding of mental health clinical services and mental health research, we have frequently observed capacity constraints within the sector that lead us to believe that many mental health clinical service providers and researchers potentially affected by the development of the table of standard costs may not yet be aware of these potential impacts. Without effective stakeholder engagement across the relevant sectors and platforms of care on behalf of IHPA, we feel that the implications of the table of standard costs on mental health research may be inadequately explored.
- The historic support for mental health research within hospital settings has also changed substantially in the last decade with the result being less environmental and institutional support available for research.
- The development of the Process Maps will be critical to cost determination on a per site, per therapeutic area basis for the majority of items within the tables. This is especially true for research in vulnerable populations. Flexibility in the application of standard costs will be required by sites in order to compare to those maps utilized by the IHPA to derive the standard costs. Site personnel will need to have a firm basis to justify any extra costs relative to a baseline assumption.

Orygen would welcome the opportunity to contribute to any interviews and focus groups aimed at engaging the youth mental health sector as part of the consultation process.

4. Response to specific items in the consultation paper

In addition to the key recommendation outlined above, we have identified a number of comments in response to specific sections of the consultation paper. These are summarised in Table 1.

Table 1: Responses to specific items in the consultation paper

CHAPTER	SECTION	REF	COMMENT
3	3.1	Dot pt 1	**Activity-based costing**: Some activities are complex. Different personnel with different unit costs conduct different components of an item. Will the process maps generated take this into account? For example, informed consent is conducted in part by a coordinator with safety/medical discussions conducted by doctors qualified to do so. Consideration should be given to making this clear for research staff.
		Dot pt 3	**Representative practice costs**: The time taken to conduct assessments can vary based on participant population. For example, under the National Statement, there are specific considerations to the conduct of research for vulnerable populations including the presence of family members/guardians/witnesses, etc. Consideration should be given to calculating costs using a per unit measure such that when items take longer or are more complex, the interval can be multiplied accordingly. The process map development in this regard will be critical. As opposed to a fee for a particular item in a particular environment (e.g. 1:1 researcher to patient may in fact be 1:3 in vulnerable populations with mental ill health). There has been some commentary to this effect in Section 3.5 although how the costs will be adjusted in not mentioned explicitly.
		Dot pt 5	**Sampling strategy:** We recommend that this should include a selection of community based mental health and health and human service organizations. Infrastructure and resourcing is different to the hospital environment as are governance considerations. This should be clarified - currently the consultation document reads as if sampling will only be through hospitals. Mental health, and specifically youth mental health operates out of the health and human services sector, principally in community settings and this sector has historically been under represented in consultations of this type or wider health-related forums. Clinical trial/research activity

			will be impacted by the IHPA deliverable and therefore we would like to engage further in the process. Sampling from the primary health services sector would be worthwhile as many research studies are operating at this interface.
		Dot pt 7	**Transparency in costing process:** It would be very useful for an example algorithm to be provided in order to allow potential users of the list to see how to derive costs. It depends on how the list has been structured, i.e. who are the end users. There are many staff at sites that have little or no experience in costing studies, so some clarity would be welcome from the end user perspective, especially for less experienced staff.
	3.2	Table 3.1, 3.2 and 3.3	Costs would be determined by who (resource, may be multiple people), how long, award rate per hour, award rate per minute. Final cost = award rate per minute x minutes labour. This will need to be determined empirically based on complexity of the study and associated documentation. It seems this logic would flow better if the last two columns were swapped over in all of the tables. This is an observation only of the table format.
		Item 1.1.1	Should read Preliminary study assessment
		Item 2.2.1	**Pre-screening activity** Consider amending wording in the 2.2.1 costing basis column to ”-per patient reviewed for study inclusion”. “Screening” in the context of clinical research means the same as current item 2.3.1.
	3.5	Page 15	See above comment on vulnerable populations. Trials in vulnerable target populations often involve consent of guardians/carers with a witness present for the entire consent discussion. This time needs to be considered and may be considered as part of the process mapping for the consent process.
			Location of trial sites: Needs to also consider different types of services community services versus acute. Fewer resources may mean more time for a particular resources for an item. Also, time of day. Standard costs do not include costing for public holidays, Sundays or

			after regular business hours e.g. night shift for many resources outside nursing and medical doctor rates.
General comments			**Process map development:** Who will develop these? It is currently unclear of the context in the current consultation document. There are many steps involved in various items and this will be critical for correctly costing resources against time.
			Consider providing some guidance in the form of algorithms to the final issued IHPA document to assist site staff in the costing process. This may also involve provision of sample process maps as they tend to be the same steps to conduct, but may utilise different resources.

In addition to these comments, we have identified a number of additional observations that may be beyond the scope of the current consultation, but which we feel may still be worth considering. These additional comments are summarised in Table 2.

Table 2: Additional comments

CHAPTER	SECTION	REF	COMMENT
3	3.2	Table 3.1	Consideration should be given to add a separate item number called Budget Determination and CTA negotiation which warrants its own item number as it is often one of the most time consuming aspects of the feasibility stage for any study. While it forms part of the ethics and SSA items, it should be stand alone as it feeds into several submissions including the Clinical Trial Agreement. In fact, the CTA process has been much simplified by the Medicines Australia standard agreement however many health services or community centres have never seen them and therefore require quite a lot of labour, training and time involvement. Please consider adding Budget Determination and CTA negotiation as separate items.
		New item	**Participant Consent.**

			Participant consent is not part of screening and can be time consuming. Screening is never conducted before gaining consent (consent process AND obtaining written consent). Therefore should be its own item. Method for costing and item assignment can be the same as listed for item 2.2.1
		New item	Annual reports to HREC is missing so is safety reporting. If these are intended to be covered by item 2.6.3, then maybe it should be mentioned explicitly. Annual reports to HRECs and SAE can be quite labour intensive. There is usually some expectation on SAEs based on the patient population. Consider adding as separate costing item.
	3.4	New item	Consider adding a new item for "Ethics and regulatory agency close out notifications"

5. Further contact

For further contact and follow up relating to this submission, please contact:

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