

South Australia

PROJECT AGREEMENT FOR ENCOURAGING MORE CLINICAL TRIALS IN AUSTRALIA

PART 1: PRELIMINARIES

1. This Schedule has been developed in accordance with clause 12(a) of the Project Agreement for Encouraging More Clinical Trials in Australia and should be read in conjunction with that Agreement.
2. This Schedule will commence as soon as it is agreed between the Commonwealth and South Australia and expire on 30 June 2021 or on completion of the project whichever is earlier, including final performance reporting and processing of final payments against milestones.

PART 2: PROJECT MILESTONES, REPORTING AND PAYMENTS

3. In accordance with clause 12 of the Agreement, the Commonwealth and South Australia have agreed a Project Plan that sets out South Australia's strategy for delivering on the outputs of the Agreement.
4. Consistent with the agreed Project Plan, South Australia will establish a state-wide Clinical Trials Coordination Unit (the CTCU) that will:
 - (a) serve as a central point of contact for sponsors, researchers, coordinators and participants;
 - (b) provide specialised support and advice services in key areas to improve efficiencies across sites;
 - (c) develop a central web portal of key clinical trials information and activities in South Australia;
 - (d) implement a new research ethics and governance management system, with enhanced data collection and reporting capability that will support expanded metrics collection and ongoing participation in national improvement efforts; and
 - (e) work with key stakeholders including the South Australian Health and Medical Research Institute, the South Australian Academic Health Science and Translation Centre, the Clinical Research Committee, universities and Local Health Networks to embed a strategic, whole-of-system, consistent and streamlined approach to clinical trials in South Australia.
5. In accordance with clause 8 and 15 of the Agreement, milestones, their relationship to outputs, expected completion dates, relevant reporting dates and expected payments are set out in Table 1.

Table 1: Milestones, reporting and payment summary

Outputs	Milestones				Reports due	Payments
	2017-18	2018-19	2019-20	2020-21		
Establish new and enhanced central coordination unit in accordance with clause 8(a) of the Agreement.	Delivery of a situational analysis on clinical trials streamlining and coordination challenges and opportunities within SA, and refinements to proposed scope and role for CTCU provided in annual performance report.	Public launch of the CTCU. Agreement by LHNs on the Good Practice Process (GPP) and distribution of revised related Standard Operating Procedures (SOPs). Delivery of a review of SA clinical trial contracting approaches, and recommendations for specialised contracting support by the CTCU.	Delivery of an analysis of publically available clinical trial resources and guidance material within SA. Public launch of web portal to promote clinical trials in SA.	Completion of monitoring and evaluation activities to identify effectiveness of, and revisions to, the CTCU.	15 May 2018 30 April 2019 30 April 2020 30 April 2021	\$241,043 \$144,653 \$144,653 \$144,653
Implement new and enhanced clinical trial data collection and reporting, in accordance with clause 8(b) of the Agreement.	Delivery of preliminary work to identify sources of data and possible methods of collection to enhance clinical trials data collection.	Full contribution of data to the expanded NAS 2018-19, as agreed by the Clinical Trials Project Reference Group (CTPRG). Contract signed with supplier of a new research ethics and governance	Full contribution of data to the expanded NAS 2019-20, as agreed by the CTPRG. Delivery of monitoring and evaluation activities to identify user and stakeholder satisfaction with the new IT system.	Full contribution of data to the expanded NAS 2020-21, as agreed by the CTPRG. Delivery of monitoring and evaluation activities to identify user and stakeholder satisfaction with the		

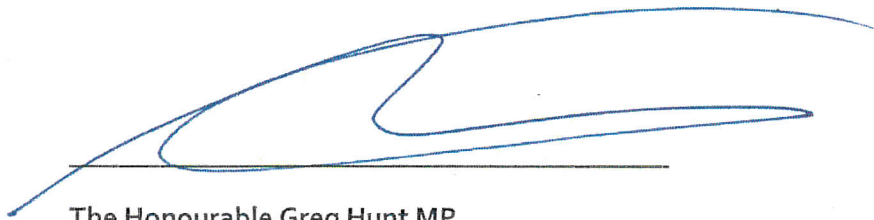
Outputs	Milestones				Reports due	Payments
	2017-18	2018-19	2019-20	2020-21		
		<p>management system, with enhanced data collection and reporting capability</p> <p>Delivery and distribution of approved and standardised clinical trial collection and reporting tools for the new system.</p> <p>Full use of the new system by all SA Human Research Ethics Committees (HRECs) and Research Governance Offices (RGOs).</p>		new IT system		
Establish and maintain new networks and partnerships in accordance with clause 8(c) of the Agreement.	Delivery of a <i>SA Health Research Focus Implementation Plan</i> and recommendations to support a strategic, systems-wide, consistent and streamlined approach to clinical trials and research governance across SA Health.	Agreement and dissemination of the <i>Research Focus Implementation Plan</i> by SA Health and relevant LHNs.	Delivery of monitoring and evaluation activities to identify continued implementation of the <i>Research Focus Implementation Plan</i> .	Delivery of monitoring and evaluation activities to identify continued implementation of the <i>Research Focus Implementation Plan</i> .		

Outputs	Milestones				Reports due	Payments
	2017-18	2018-19	2019-20	2020-21		
Embed research and clinical trials processes in accordance with clause 8(d) of the Agreement.	Active engagement with CTPRG, Commonwealth and ACSQHC to develop a draft Clinical Trials Governance Framework.	Active engagement with CTPRG, Commonwealth and ACSQHC to develop a draft Clinical Trials Governance Framework.	Active engagement with CTPRG, Commonwealth and ACSQHC to implement the national Clinical Trials Governance Framework.	Active engagement with CTPRG, Commonwealth and ACSQHC to implement the national Clinical Trials Governance Framework.		

SIGN OFF

The Parties have confirmed their commitment to this Schedule as follows:

Signed for and on behalf of the Commonwealth of Australia by



The Honourable Greg Hunt MP

Minister for Health

12/4/2018

Signed for and on behalf of the State of South Australia by



The Honourable Stephen Wade MP

Minister for Health and Wellbeing

27/5/2018