

# Victoria

## 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 Victoria (VIC) and expires 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 VIC have agreed a Project Plan that sets out VIC's strategy for delivering on the outputs of the Agreement.
4. Consistent with the agreed Project Plan, VIC will expand the functions of its state-wide Coordinating Office for Clinical Trial Research (Coordinating Office (DHHS)) that will:
  - (a) provide a centralised 'front door' for trial sites and clinical trial units in 11 leading teaching hospitals and provide information and referral;
  - (b) work with a professional consulting service to develop a 'model' for central clinical trial units at the hospital level to serve as primary points of contact and centres of excellence in trial conduct, planning and support;
  - (c) establish a buddy system to partner primary points of contact with secondary hospitals in regional settings to ensure full geographic coverage, working collaboratively with the Department of Health and Human Services clinical and other networks, Safer Care Victoria, Monash Partners and Melbourne Partners;
  - (d) test two pilot sites and undertake a consultation process to inform final model development and a strategy for implementation and full state-wide establishment once additional funding sources become available; and
  - (e) continue to enhance and expand clinical trials data capture and reporting capability at the central point of contact and state-wide levels, which will support continued participation in national data improvement efforts.
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.	<p>Delivery of expanded functions within the state-wide Coordinating Office for Clinical Trial Research to provide a centralised front door for trial sites and clinical trial units in 11 leading teaching hospitals, including information and referral.</p> <p>Signed contract for delivery of professional consultation services.</p> <p>Commencement of stakeholder consultations on development of central model for clinical trials management and administration hubs in public health services.</p>	<p>Delivery of consultancy report, including key findings and proposed model for clinical trials management and administration hubs.</p> <p>Confirmation of pilot sites for trialling of the proposed model.</p>	<p>Implementation of the proposed central model for clinical trials management and administration hubs in public health services at two pilot sites.</p> <p>Delivery of preliminary summary of findings from pilot studies.</p>	<p>Delivery of report on professional evaluation of the pilot studies, including proposed refinements to the model and planning for ongoing implementation.</p>	<p>15 May 2018</p> <p>15 May 2019</p> <p>15 May 2020</p> <p>15 May 2021</p>	<p>\$357,100</p> <p>\$214,300</p> <p>\$214,300</p> <p>\$214,300</p>
Implement new and enhanced clinical trial data collection and reporting, in accordance with clause 8(b) of the Agreement.	<p>Full contribution of data to the National Aggregate Statistics (NAS) 2017-18, as agreed by the Clinical Trials Project Reference Group (CTPRG).</p>	<p>Full contribution of data to the expanded NAS 2018-19, as agreed by the CTPRG. Launch of new generation ethics and governance</p>	<p>Full contribution of data to the expanded NAS 2019-20, as agreed by the CTPRG.</p> <p>Delivery of data reports from pilot sites</p>	<p>Full contribution of data to the expanded NAS 2020-21, as agreed by the CTPRG.</p>		

Outputs	Milestones				Reports due	Payments
	2017-18	2018-19	2019-20	2020-21		
	<p>Delivery of new generation system for ethics and governance administration and reporting, with connection to Queensland Health platform.</p> <p>Delivery of modifications to VIC data warehouse to enable integration with NAS additional metrics, and data definitions system for VIC data warehouse system reporting.</p>	<p>administration and reporting system.</p> <p>Measure number of users trained in new generation system.</p>	<p>testing provision of clinical trial recruitment and financial investment data.</p>			
<p>Establish and maintain new networks and partnerships in accordance with clause 8(c) of the Agreement.</p>	n/a	<p>Identification of regional buddies to participate in pilot studies</p>	<p>Participation of regional buddies in pilot studies</p>	<p>Active engagement of regional buddies in planning for ongoing implementation.</p>		
<p>Embed research and clinical trials processes in accordance with clause 8(d) of the Agreement.</p>	<p>Active engagement with the Clinical Trials Project Reference Group (CTPRG), Commonwealth and ACSQHC to develop a draft Clinical Trials Governance Framework.</p>	<p>Active engagement with CTPRG, Commonwealth and ACSQHC to develop a draft Clinical Trials Governance Framework.</p>	<p>Active engagement with CTPRG, Commonwealth and ACSQHC to implement the national Clinical Trials Governance Framework.</p>	<p>Active engagement with CTPRG, Commonwealth and ACSQHC to implement the national Clinical Trials Governance Framework.</p>		

**SIGN OFF**

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

*Signed for and on behalf of the Commonwealth of Australia by*

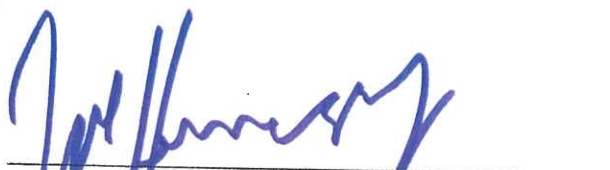
A large, stylized handwritten signature in blue ink, written over a horizontal line. The signature is cursive and appears to read 'Greg Hunt'.

**The Honourable Greg Hunt MP**

Minister for Health

12/4/2018

*Signed for and on behalf of the State of Victoria by*

A large, stylized handwritten signature in blue ink, written over a horizontal line. The signature is cursive and appears to read 'Jill Hennessy'.

**The Honourable Jill Hennessy MP**

Minister for Health

10/5/2018