

Australian Capital Territory

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 the Australian Capital Territory (ACT) 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 ACT have agreed a Project Plan that sets out ACT's strategy for delivering on the outputs of the Agreement.
4. Consistent with the agreed Project Plan, ACT will expand the recently established state-wide ACT Centre for Clinical Trials (CCT) that will:
 - (a) act as a central point of contact for sponsors, researchers, coordinators and participants;
 - (b) provide centralised support and coordination of all public sector clinical trials within ACT, including development of streamlined mechanisms to enable New South Wales (NSW) residents to participate in ACT based trials;
 - (c) develop and implement an innovative Information and Communication Technology (ICT) platform that will enhance clinical trial data and recruitment capability, and support efficient translation of research outcomes into practice improvement; and
 - (d) introduce a research mentorship program for new and early career researchers to enhance capability and research activity within ACT.
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

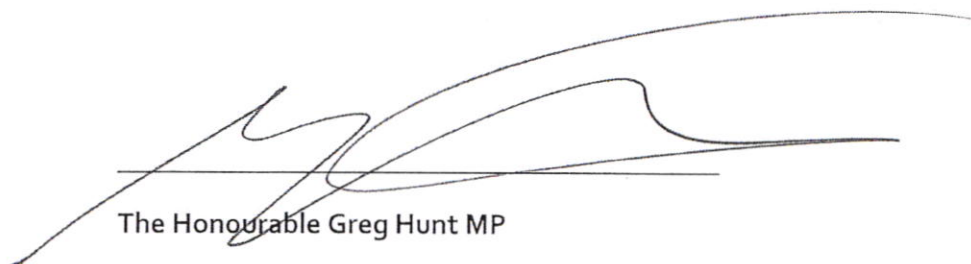
Outputs	Milestones				Reports due	Payments
	2017-18	2018-19	2019-20	2020-21		
Establish new and enhanced central coordination unit in accordance with clause 8(a) of the Agreement.	<p>Delivery of a project to inform system redesign and findings provided in annual performance report.</p> <p>Delivery of a clinical trials scorecard to assess ACT trial activity and inform strategic directions of future trials investments and partnerships in ACT</p> <p>Publication and distribution of revised Standard Operating Procedures (SOPs) for trials in the ACT.</p>	<p>Delivery and public launch of a Single Point of Contact (SPC) for all clinical trials entering ACT.</p> <p>Signed agreements with the Australian National University, University of Canberra, university partners and other public and private health organisations to centralise coordination and management of trial conduct (including cross-institutional research governance) through the CCT.</p>	<p>Delivery of an increase in permanent clinical trial coordinator positions in ACT compared to baseline.</p> <p>Delivery of a new policy to support stable and sustainable employment for clinical trial coordinators.</p>	<p>Delivery of survey and review of Standard Operating Procedures (SOPs) for all ACT clinical trials, and update and publication of revised SOPs informed by review outcomes.</p> <p>Signed agreements with all ACT CCT partners to enable centralised management and coordination of clinical trials within ACT.</p>	<p>30 April 2018</p> <p>30 April 2019</p> <p>30 April 2020</p> <p>30 April 2021</p>	<p>\$255,237</p> <p>\$153,225</p> <p>\$153,225</p> <p>\$153,225</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>Signed contract with vendor for development of</p>	<p>Full contribution of data to the expanded NAS 2018-19, as agreed by the CTPRG.</p> <p>Delivery of beta testing of innovative ICT system.</p>	<p>Full contribution of data to the expanded NAS 2019-20, as agreed by the CTPRG.</p> <p>All clinical trials within reach of CCT captured within innovative ICT</p>	<p>Full contribution of data to the expanded NAS 2020-21, as agreed by the CTPRG.</p> <p>NAS data requirements and automated reporting</p>		

Outputs	Milestones				Reports due	Payments
	2017-18	2018-19	2019-20	2020-21		
	innovative Information and Communication Technology (ICT) platform that will enhance clinical trial data and recruitment capability and support efficient translation of research outcomes into practice improvement.		system.	capability incorporated into innovative ICT system.		
Establish and maintain new networks and partnerships in accordance with clause 8(c) of the Agreement.	Signed agreement between ACT and NSW to facilitate collaboration on development and operation of a shared research ethics and governance information management system in partnership with NSW.	Signed Agreement between ACT and NSW to streamline administrative functions and trial pathways to support cross-border trial participation, including to enable NSW regional residents to participate in ACT based trials.	Signed agreement by ACT Health and the John Curtin School of Medical Research, ANU to facilitate translation of research into patient care and service improvement.	Nil		
Embed research and clinical trials processes in accordance with clause 8(d) of the Agreement.	Active engagement with the Clinical Trials Project Reference Group (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

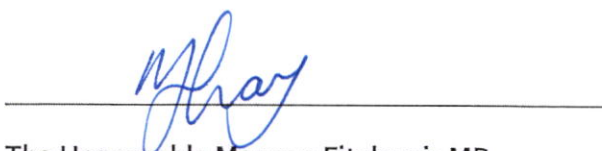
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The Honourable Greg Hunt MP

Minister for Health

12/4/2018

Signed for and on behalf of the State of Australian Capital Territory by

A handwritten signature in blue ink, written over a horizontal line. The signature is cursive and appears to read 'M Fitzharris'.

The Honourable Meegan Fitzharris MP

Minister for Health

3/15/2018