Tasmania

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 Tasmania 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 Tasmania have agreed a Project Plan that sets out Tasmania's strategy for delivering on the outputs of the Agreement.

4. Consistent with the agreed Project Plan, Tasmania will establish and embed a state-wide Research Governance Office (RGO) within the Department of Health and Human Services (DHHS) that will:

   (a) function as a central point of contact for sponsors, researchers, participants, research institutes and other stakeholders supported by a Research Governance Framework and communication strategy;

   (b) build on Tasmania's existing single ethical review process, and leverage off work that other jurisdictions have already undertaken, to develop a single system-wide Research Strategy and introduce unified processes across the state to improve system navigation, cohesion, streamlining and capacity;

   (c) develop and implement a state-wide Information and Communication Technology (ICT) platform that will enhance clinical trial data, provide research governance management and external reporting, and support efficient translation of research outcomes into practice improvement; and

   (d) establish strategic linkages with Ambulance Tasmania, the Tasmania Health Service (THS), the University of Tasmania (UTAS), the Menzies Institute for Medical Research, the Clifford Craig Research Foundation and the Royal Hobart Hospital Research Foundation.

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.	Complete a scoping analysis of current stakeholders and activities to inform establishment of the state-wide Research Governance Office (RGO) in the Department of Health and Human Services (DHHS) as a central point of contact for all clinical trial sponsors, researchers, coordinators and participants entering TAS.	Establish and publically launch the RGO. Complete a state-wide Research Governance Framework (RGF), including scoping of long term research governance resource requirements, to inform development of a state-wide Research Strategy. Complete a state-wide communication strategy on the RGO's scope, and stakeholder's roles and responsibilities. Publication on the DHHS intranet (internal website) of state-wide RGF including SOPs and guidelines.	Complete and publically launch a state-wide Research Strategy, including partnership approaches between public and private research institutions, and approaches to increase the clinical trial research capacity of sector staff.	Complete public (external) reporting against the Research Strategy.	15 May 2018 15 May 2019 15 May 2020 15 May 2021	$119,629 $71,791 $71,791 $71,791

Implement new and enhanced clinical trial data collection and reporting, in accordance with clause 8(b) of the Agreement.	Nil	Contribution of data to the expanded National Aggregate Statistics (NAS) 2018-19, as agreed by the Clinical Trials Project Reference Group (CTPRG). Complete a scoping report of IT systems (including sub-site options) for system-wide research governance management and external reporting. Complete state-wide and any required inter-state agreements on the IT system.	Full contribution of data to the expanded NAS 2019-20, as agreed by the CTPRG. Implement the agreed system-wide research governance management and external reporting system.	Full contribution of data to the expanded NAS 2020-21, as agreed by the CTPRG.		
Establish and maintain new networks and partnerships in accordance with clause 8(c) of the Agreement.	Nil	Establish and maintain a Research Committee, to include Tasmanian stakeholders involved in research ethics and clinical trials governance processes.	Full participation in the National Mutual Acceptance (NMA) scheme. Strengthened agreement with the Menzies Institute for Medical Research on collaborative strategic approaches. Signed agreement	Nil		

			with the Clifford Craig Research Foundation and the Royal Hobart Hospital Research Foundation on collaborative strategic approaches.			
Embed research and clinical trials processes in accordance with clause 8(d) of the Agreement.	Active engagement with the 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

30/5/2018

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

The Honourable Michael Ferguson MP

Minister for Health

27/6/2018