

# Northern 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 Northern Territory (NT) 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 NT have agreed a Project Plan that sets out NT's strategy for delivering on the outputs of the Agreement.
4. Consistent with the agreed Project Plan, NT will consolidate and expand existing functions to establish a central point of contact (unit) for clinical trial sponsors, researchers, coordinators and participants that will:
  - (a) provide a single point of application for research ethics and site specific approvals;
  - (b) provide a centralised source of advice and facilitate the introduction of standard operating procedures across all Northern Territory Department of Health sites, informed by strong Indigenous leadership, to support and encourage best practice and culturally appropriate research and recruitment, including for vulnerable populations;
  - (c) enhance clinical information systems and Information and Communication Technology (ICT) capability to assist clinical trial recruitment, and to facilitate NT participation in ongoing national reporting and streamlining activities; and
  - (d) work with comparable units in Queensland and Western Australia to establish a formal partnership arrangement to attract and support Northern Australia clinical trials, drawing on existing expertise in key research institutions and national clinical trials networks to inform and encourage high-quality national and international trials.
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>Establish and publically launch the Northern Territory Clinical Trials Coordination Unit (NTCTCU), as a central point of contact for all clinical trial sponsors, researchers, coordinators and participants entering NT.</p> <p>Finalise agreement within NT Health on centralised functions of NTCTCU.</p> | <p>Public launch of the NTCTCU website, including a single submission format and location for NT Clinical Trials and Human Research Ethics (HREC) applications.</p> <p>Implement revised NT Health-wide research governance processes.</p> <p>Design and conduct trial of community consultations.</p> <p>Finalise and distribute a single Standard Operating Procedure (SOP) for all clinical trials across NT Health sites, informed by strong Aboriginal leadership.</p> | <p>All NT Health clinical trials coordinated by the NTCTCU and enter via the NTCTCU website.</p> <p>Consolidation of new clinical trials operating systems and governance mechanisms within NT Health operations.</p> | <p>Complete a NT research needs assessment (including translational research), aligned with strategic priorities of the NT Department of Health and two Health Services.</p> <p>Complete monitoring and evaluation activities to identify impact, effectiveness of, and revisions to, the NTCTCU, including coordination of the clinical trial pathway.</p> | <p>30 April 2018</p> <p>30 April 2019</p> <p>30 April 2020</p> <p>30 April 2021</p> | <p>\$241,043</p> <p>\$144,553</p> <p>\$144,553</p> <p>\$144,553</p> |

| Outputs   | Milestones |  |   |  | Reports due | Payments |
|---|------------|--|---|--|-------------|----------|
|   | 2017-18    | 2018-19  | 2019-20   | 2020-21  |             |          |
| Implement new and enhanced clinical trial data collection and reporting, in accordance with clause 8(b) of the Agreement. | n/a        | <p>Full contribution of data to the expanded National Aggregate Statistics (NAS) 2018-19, as agreed by the Clinical Trials Project Reference Group (CTPRG).</p> <p>Commence mapping of data extraction capability in the Core Clinical System Renewal Program (CCSRP), including capacity to collect total numbers of patients potentially eligible for trials.</p> <p>Finalise and implement an IT system for internal clinical trials management and external reporting.</p> | <p>Full contribution of data to the expanded NAS 2019-20, as agreed by the CTPRG.</p> <p>Capture all clinical trials within reach of NTCTCU within IT system.</p> | <p>Full contribution of data to the expanded NAS 2020-21, as agreed by the CTPRG.</p> <p>Capture data on recruitment as a proportion of all eligible patients.</p> |             |          |

| Outputs   | Milestones  |  |         |   | Reports due | Payments |
|---|---|--|---------|---|-------------|----------|
|   | 2017-18   | 2018-19  | 2019-20 | 2020-21   |             |          |
| Establish and maintain new networks and partnerships in accordance with clause 8(c) of the Agreement. | Establish and maintain a Project Steering Committee, to include all NT stakeholders involved in research ethics and clinical trials governance processes. | Deliver promotional activities to raise awareness of the NTCTCU. | n/a     | <p>Finalise agreement between NT, Queensland and Western Australia to attract and support Northern Australian clinical trials that seek to address public health priorities and areas of significant disease burden that contribute to the continuing gap in life expectancy between non-Indigenous and Indigenous Australians.</p> <p>Completion of NTCTCU's NT research needs assessment and evaluation, with recommendations for sustainable research structures that meet population needs.</p> |             |          |

| 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 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*



**The Honourable Greg Hunt MP**

Minister for Health

24/4/2018

*Signed for and on behalf of the State of the Northern Territory by*



**The Honourable Natasha Fyles MP**

Minister for Health

/ /2018

-7 JUN 2018