PROJECT AGREEMENT FOR ENCOURAGING MORE CLINICAL TRIALS IN AUSTRALIA

An agreement between:

- the **Commonwealth of Australia;** and
- the **States and Territories of**
  - New South Wales,
  - Victoria,
  - Queensland,
  - Western Australia,
  - South Australia,
  - Tasmania,
  - the Australian Capital Territory, and
  - the Northern Territory.

The outputs of this project will be the redesign of clinical trials systems.

Project Agreement for Encouraging More Clinical Trials in Australia

OVERVIEW

1. This Project Agreement (the Agreement) is created subject to the provisions of the Intergovernmental Agreement on Federal Financial Relations (IGA FFR) and should be read in conjunction with that Agreement and its Schedules, which provide information in relation to performance reporting and payment arrangements under the IGA FFR.

Purpose

2. This Agreement will encourage more clinical trials in Australia by supporting:

   (a) the redesign of clinical trials systems, with a focus on the establishment of central coordination units to better organise clinical trials sites, streamline clinical trials processes and make it easier to conduct and participate in safe, high quality clinical trials; and new networks and partnerships;

   (b) new and enhanced clinical trial data collection and reporting;

   (c) improvements to core hospital governance arrangements; and

   (d) a consistent and cohesive national approach to the conduct of clinical trials in accordance with the Principles and agreed Priority Action Areas as endorsed by the Council of Australian Governments Health Council in March 2017.

Reporting Arrangements

3. The States will report annually against the agreed milestones during the operation of this Agreement, as set out in Part 4 – Project Milestones, Reporting and Payments.

Financial Arrangements

4. The Commonwealth will provide an estimated total financial contribution to the States of $7 million nationally, exclusive of GST, in respect of this Agreement, as set out in Part 5 – Financial Arrangements.

PART 1 – FORMALITIES

5. This Agreement and its bilateral Schedules constitute the entire agreement for this project.

Parties to this Agreement

6. This Agreement is between the Commonwealth of Australia (the Commonwealth) and the States and Territories (the States).

Term of the Agreement

7. This Agreement will commence as soon as the Commonwealth and one other Party sign it and will expire on 30 June 2021 or on completion of the project, including final performance reporting and processing of final payments against milestones, unless terminated earlier or extended as agreed in writing by the Parties.

PART 2 – PROJECT OUTPUT

Output

8. The output of this Agreement will be the redesign of clinical trials systems through:

   (a) establishing new and enhanced central coordination units or equivalent that will:

      i. play a key 'gateway' role for sponsors, investigators, referrers and participants accessing and navigating trials;

      ii. reduce the administrative load on trial sites through the provision and/or facilitation of key trial operational functions (e.g., feasibility assessment, ethics clearance, site authorisation, trial governance, insurance and contract management);

      iii. act as central points for communication, training and education;

      iv. support patient recruitment and the conduct of clinical trials;

      v. support the clinical trial workforce through building capacity and capability, ensuring quality control and pooling resources to provide career pathways and professional development; and

      vi. work across jurisdictions towards a consistent and cohesive national approach to the conduct of clinical trials, including implementing agreed standards;

   (b) implementing new and enhanced clinical trial data collection and reporting to inform systems improvement with interoperability and data flow capability, and contribute to better sector knowledge, recruitment and overall sector performance including through:

      i. implementation and continued expansion of clinical trials metrics collection including those agreed under the Framework for National Aggregate Statistics (NAS); and

      ii. ongoing submission of agreed metrics to the national data collection in accordance with the Framework for NAS;

   (c) establishing and maintaining new networks and partnerships within and between jurisdictions, clinical trial networks, communities of practice (eg. oncology, working with ATSI groups) and registries; and

   (d) embedding research and clinical trials processes into core hospital governance arrangements.

9. The States are collectively responsible for delivering these outputs, which reflect the revitalised clinical trials agenda endorsed by Health Ministers in March 2017. In support of these outputs, each jurisdiction is responsible for delivering the projects agreed in its bilateral Schedule to this Agreement.

PART 3 – ROLES AND RESPONSIBILITIES OF EACH PARTY

Role of the Commonwealth

10. The Commonwealth will be responsible for:

    (a) monitoring and assessing achievement against milestones in the implementation of this Agreement to ensure that outputs are delivered within the agreed timeframe; and

    (b) providing a consequent financial contribution to the States to support the implementation of this Agreement.

Role of the States

11. The States will be responsible for:

    (a) all aspects of delivering on the project outputs set out in this Agreement;

    (b) developing Project Plans in consultation with the Commonwealth and in accordance with clauses 12 and 13 of this Agreement; and

    (c) reporting on the delivery of outputs as set out in Part 4 – Project Milestones, Reporting and Payments and the schedules to this Agreement.

Shared roles

12. The Commonwealth and the States will be responsible for:

    (a) developing and agreeing bilateral schedules to this Agreement which set out milestones, reporting and payment arrangements in accordance with Part 4 – Project Milestones, Reporting and Payments;

    (b) agreeing Project Plans in accordance with clauses 11 and 13 of this Agreement;

    (c) working with the Australian Commission on Safety and Quality in Healthcare (ACSQHC) to develop a governance framework for clinical trials in public hospitals to ensure governance processes are robust and meet appropriate standards; and

    (d) meeting the requirements of Schedule E, Clause 26 of the IGA FFR, by ensuring that prior agreement is reached on the nature and content of any events, announcements, promotional material or publicity relating to activities under this Agreement, and that the roles of both Parties will be acknowledged and recognised appropriately.

Project Plans

13. Within two months of the execution of this Agreement the Commonwealth and the States will agree to Project Plans that will set out each State's strategy for delivering on the outputs of this Agreement.

14. Project Plans will be flexible documents that may be varied to accommodate changed circumstances. Any variations to Project Plans that impact on milestones and payments under this Agreement will be subject to arrangements set out in clause 25 of this Agreement. Other variations or updates to Project Plans are subject to the agreement of senior Commonwealth and State officials.

PART 4 – PROJECT MILESTONES, REPORTING AND PAYMENTS

15. The milestones for the project, their relationship to the outputs, expected completion dates, relevant reporting dates and expected payments to be made are set out in bilateral schedules to this Agreement. The Commonwealth will make payments subject to the performance reports demonstrating the relevant milestones have been met.

16. If a milestone is met in advance of the due date, where the relevant performance report demonstrates that the milestone has been met, the Commonwealth may make the associated payment earlier than scheduled provided it falls within the same financial year as the original milestone date.

Reporting arrangements

17. The States will provide annual performance reports in accordance with Schedules A - H during the operation of the Agreement. Each performance report is to contain a description of actual performance in the period to date against the project milestones, and provide an update on activities undertaken as outlined in each State's Project Plan.

18. Progress Reports will not be published however a consolidated summary of overall progress may be released periodically.

PART 5 – FINANCIAL ARRANGEMENTS

19. The Commonwealth will provide an estimated total financial contribution to the States of $7 million respect of this Agreement. All payments are GST exclusive.

20. The Commonwealth will provide $50,000 to each State on signing of this Agreement to assist with start-up costs associated with delivering the outputs of this Agreement.

21. The Commonwealth's funding contribution will not be reduced where the States secure funding from other activity partners.

22. The Commonwealth's and the States' estimated financial contributions to the operation of this Agreement, including through National Partnership payments to the States paid in accordance with *Schedule D — Payment Arrangements* of the IGA FFR, are shown in Table 1.

Table 1: Estimated financial contributions

($)	2017-18	2018-19	2019-20	2020-21	Total
Estimated total budget	**2,500,000**	**1,500,000**	**1,500,000**	**1,5000,000**	**7,000,000**
New South Wales	500,240	300,020	300,020	300,020	1,400,300
Victoria	357,100	214,300	214,300	214,300	1,000,000
Queensland	428,520	257,160	257,160	257,160	1,200,000
Western Australia	357,100	214,300	214,300	214,300	1,000,000
South Australia	241,043	144,653	144,653	144,653	675,000
Tasmania	119,629	71,791	71,791	71,791	335,000
Australian Capital Territory	255,327	153,225	153,225	153,225	715,000
Northern Territory	241,043	144,553	144,553	144,553	674,700
Less estimated National Partnership Payments	2,500,000	1,500,000	1,500,000	1,5000,000	7,000,000
Balance of non-Commonwealth contributions[(a)]	0.0	0.0	0.0	0.0	0.0

[(a)] States are not required to provide financial and in-kind contributions under the terms of this Agreement. However, as States are responsible for the provision of public hospital services, they allocate their own source funding and provide in-kind contributions accordingly, including in support of activities funded under this Agreement.

23. Having regard to the agreed estimated costs of projects specified in this Agreement, a State or Territory will not be required to pay a refund to the Commonwealth if the actual cost of the project is less than the agreed estimated cost of the project. Similarly, the States bear all risk should the costs of a project exceed the agreed estimated costs. The Parties acknowledge that this arrangement provides the maximum incentive for the States to deliver projects cost effectively and efficiently.

PART 6 – GOVERNANCE ARRANGEMENTS

Enforceability of the Agreement

24. The Parties do not intend any of the provisions of this Agreement to be legally enforceable. However, that does not lessen the Parties' commitment to this Agreement.

Variation of the Agreement

25. The Agreement may be amended at any time by agreement in writing by all the Parties.

26. Bilateral schedules to this Agreement that have no impact on other Parties may be amended at any time by agreement in writing by the relevant Commonwealth and State portfolio ministers.

27. A Party to the Agreement may terminate their participation in the Agreement at any time by notifying all Parties in writing.

Delegations

28. The Commonwealth Minister may delegate the assessment of performance against milestones and the authorisation of related project payments to senior Commonwealth officials, having regard to the financial and policy risks associated with those payments.

Dispute resolution

29. Any Party may give notice to other Parties of a dispute under this Agreement.

30. Officials of relevant Parties will attempt to resolve any dispute in the first instance.

31. If a dispute cannot be resolved by officials, it may be escalated to the relevant Ministers.

Interpretation

32. For the purposes of this Agreement:

(a) Approaches to clinical trials system redesign will be in accordance with the following Principles and agreed Priority Action Areas as endorsed by the Council of Australian Governments Health Council in March 2017:

i. Principles
- i.i The patient is at the centre of clinical trials.
- i.ii Research and clinical trials are essential health system activities.
- i.iii Clinical trials foster a culture of quality, safety and innovation.
- i.iv Access for patients must be made easier – participation, navigation and delivery.
- i.v Partnerships and collaboration are at the core of any success.
- i.vi Workforce support is central - capacity, capability and predictability, career pathways.
- i.vii Knowledge and transparency – KPIs, data, accountability, value offer.

ii. Priority Action Areas
- ii.i Clinical Trials Coordination Units.
- ii.ii Clinical Trials Networks and Partnerships.
- ii.iii Enhancement of clinical trials data and knowledge systems.
- ii.iv Research as essential health system business.
- ii.v Introduce clinical trials governance into Australian Commission for Safety and Quality in Health Care's National Safety and Quality Standards.

(b) The Framework for National Aggregate Statistics (NAS) represents agreement by all states on the essential metrics to monitor and drive improvements to clinical trials in Australia. The NAS Framework was endorsed by the Council of Australian Governments Health Council in April 2015, including agreement that the NAS Framework would be refined over time to reflect changing priorities and data availability.

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

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

The Honourable Greg Hunt MP
Minister for Health

[Day] [Month] [Year] 13 MAR 2018

Signed *for and on behalf of the State of New South Wales by*

The Honourable Brad Hazzard MP
Minister for Health

[Day] [Month] [Year]

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

The Honourable Jill Hennessy MP
Minister for Health

[Day] [Month] [Year]

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

The Honourable Cameron Dick MP
Minister for Health

[Day] [Month] [Year]

Signed *for and on behalf of the State of Western Australia by*

The Honourable Roger Hugh Cook MP
Minister for Health

[Day] [Month] [Year]

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

The Honourable Peter Malinauskas MLC
Minister for Health

[Day] [Month] [Year]

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

The Honourable Michael Ferguson MP
Minister for Health

[Day] [Month] [Year]

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

The Honourable Meegan Fitzharris MP
Minister for Health

[Day] [Month] [Year]

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

Natasha

The Honourable Natasha Fyles MLA
Minister for Health

[Day] [Month] [Year]

5 JAN 2018

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

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

The Honourable Greg Hunt MP
Minister for Health

[Day] [Month] [Year]

Signed *for and on behalf of the State of New South Wales by*

The Honourable Brad Hazzard MP
Minister for Health

[Day] [Month] [Year]

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Minister for Health

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The Honourable Roger Hugh Cook MP
Minister for Health

[Day] [Month] [Year]

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The Honourable Peter Malinauskas MLC
Minister for Health

[Day] [Month] [Year]

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

The Honourable Michael Ferguson MP
Minister for Health 16/1/2018

[Day] [Month] [Year]

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

The Honourable Meegan Fitzharris MP
Minister for Health

[Day] [Month] [Year]

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

The Honourable Natasha Fyles MLA
Minister for Health

[Day] [Month] [Year]

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Minister for Health

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Minister for Health

[Day] [Month] [Year]

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The Honourable Cameron Dick MP
Minister for Health

[Day] [Month] [Year]

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The Honourable Roger Hugh Cook MP
Minister for Health

[Day] [Month] [Year]

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The Honourable Peter Malinauskas MLC
Minister for Health

[Day] [Month] [Year]

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The Honourable Michael Ferguson MP
Minister for Health

[Day] [Month] [Year]

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

The Honourable Meegan Fitzharris MP
Minister for Health

[Day] [Month] [Year]
22/2/2018

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

The Honourable Natasha Fyles MLA
Minister for Health

[Day] [Month] [Year]

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Minister for Health

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The Honourable Meegan Fitzharris MP
Minister for Health

[Day] [Month] [Year]

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

The Honourable Jill Hennessy MP
Minister for Health

[Day] [Month] [Year]
10/5/2018

Signed *for and on behalf of the State of Western Australia by*

The Honourable Roger Hugh Cook MP
Minister for Health

[Day] [Month] [Year]

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

The Honourable Michael Ferguson MP
Minister for Health

[Day] [Month] [Year]

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The Honourable Natasha Fyles MLA
Minister for Health

[Day] [Month] [Year]

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Minister for Health

[Day] [Month] [Year]

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

The Honourable Steven Miles MP
Minister for Health

[Day] [Month] [Year]

Signed *for and on behalf of the State of Western Australia by*

The Honourable Roger Hugh Cook MP
Minister for Health

[Day] [Month] [Year]

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

Stephen Wade

The Honourable Stephen Wade MP
Minister for Health and Wellbeing

[Day] [Month] [Year]
02 05 2018

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

The Honourable Michael Ferguson MP
Minister for Health

[Day] [Month] [Year]

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

The Honourable Meegan Fitzharris MP
Minister for Health

[Day] [Month] [Year]

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The Honourable Natasha Fyles MLA
Minister for Health

[Day] [Month] [Year]

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Minister for Health

[Day] [Month] [Year]

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

The Honourable Steven Miles MP
Minister for Health

[Day] [Month] [Year]
12 June 2018

Signed *for and on behalf of the State of Western Australia by*

The Honourable Roger Hugh Cook MP
Minister for Health

[Day] [Month] [Year]

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[Day] [Month] [Year]
12 JUN 2018

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