Agreement for Funding of Services

Schedule

15 June 2018

NSW Health Early Phase Clincal Trial HREC

Office for Health and Medical Research, Ministry for Health
ABN [#Insert ABN]

[#Insert name of Provider]
ABN [#Insert ABN]

The Date of the Agreement is [#Insert date of execution from Execution page]

This Schedule is to be read in conjunction with the Agreement for Funding of Services - Standard Terms.

Capitalised terms, where used in this Schedule, have the same meaning as given in the Agreement for Funding of Services - Standard Terms, unless the context requires otherwise.

Details	Description	
Us (Agency)	Name:	NSW Ministry for Health
	ABN:	[#Insert Agency ABN]
	Address:	Level 5, 73 Miller St, North Sydney NSW 2060
	Position, name and contact details of Agency representative:	Dr Antonio Penna, Executive Director Office for Health and Medical Research
You (Provider)	Name:	[#Insert Provider's name]
	ABN/ACN/ICN:	[#Insert Provider's Australian Business Numner / Australian Company Number / Indigenous Corporation Number (as applicable)]
	Address:	[#Insert Provider's address]
	Position, name and contact details of Provider representative:	[#Insert position, name and contact details (including email address) of the Provider's representative]
Initial Term (Clauses 1.1 and 3.1)	3 years	
Extension period (Clause 3.2)	3 years, conditional upon review of performance milestones and at the discretion of the Deputy Secretary, Chief Health Officer, NSW Ministry for Health.	
Services (Clauses 1.1 and 5)	The NSW Health Early Phase Clinical Trial HREC will: 1. *On transition to the new business arrangements (December 2018-April 2019)* • Continue to fulfil their standard role in reviewing research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines. • Ensure appropriate change management activities to transition to the new operational arrangements to meet the above timeframes. Submit a change management plan to Office for Health and Medical Research, NSW Ministry of Health.	

Details	Description
	• Agree on the standard premium fees for early phase clinical trial applications for commercially sponsored trials and Investigator led trials. (Fees will be determined upon discussion and negotiation with all the appointed NSW Health early phase clinical trials HREC prior to commencing services) • HREC Chairs and other relevant staff attend meetings to jointly shape the scheme in this transitional phase and to advise the Agency *2. When providing ethics review for early phase clinical trials (April 2019 – 2022)* • Provide safe and high quality scientific and ethics review of all early phase clinical trials applications within 30 working days benchmark- (and working towards 20 –working days) (defined by days 'on the clock' from submission closing date to initial review decision) and all amendments within 10 working days. • Conduct ethics review in accordance with agreed intentions of the HREC Scheme and the standard operating procedures agreed with the NSW Health early phase clinical trials HRECs. • Contribute to capacity building and continuous professional development including education and training • Collect and collate the data to monitor the operations of the HREC in accordance with the Annual milestone reporting • Submit an annual milestone report in April each year from April 2020. *3. When contributing to the quality assurance of the scheme (December 2018 – April 2022)* • Work in harmonisation with other NSW Health early phase clinical trial HRECs to conduct the ethics review of the early phase clinical trial applications. • HREC Chairs and other relevant staff meeting six monthly to discuss and advise the Agency on the NSW Health early phase clinical trial HREC Scheme.
Target Group (Clauses 1.1 and 5.1(a)(i))	The NSW Health Early Phase Clinical Trial HREC will provide ethics review services to investigator lead and commercially sponsored early phase clinical trial research projects.
Objectives (Clauses 1.1 and 5.1(a)(v))	In providing these services the NSW Health Early Phase Clinical Trial HREC is ensuring timely and high quality processes for the approval to commence early phase trials in NSW.
Funds and payment (Clauses 1.1 and 9.1)	Total amount of Funds: (Clauses 1.1 and 9.1(a)) — Up to $50,000 (exclusive of GST) as a one off payment in the first year to support change management. Up to $50,000 (exclusive of GST) per annum for three years. (Sum to be confirmed following review of applications)

Details	Description
The Funds will be paid to You on the following basis: (Clause 9.1(a))	Payment is at the discretion of the Executive Director OHMR. Payment is subject to submission of milestone reports and satisfactory performance against the Services and/or undertaking of remedial action to improve performance. At the end of the three year funding period a final milestone report will be due. The report will inform and decision to extend the Agreement for a further three years.

Instalment	Payment trigger	Date for payment	Supporting documentation for payment claim
1. $75,000	**Change Management Plan**	**November 2018**	**Change Management Plan for timelines Benchmark**
2. $25,000	**Performance assessment**	**Jul 2019**	**Outcomes of Change Management Plan**
3. $50,000	**Performance assessment**	**Jul 2020**	**1st Milestone report – April 2020 and the NHMRC annual report**
4. $50,000	**Performance assessment**	**Jul 2021**	**2nd Milestone report – April 2021 and the NHMRC annual report**
5. NIL	**Performance review**	**NIL**	**Final Milestone report – April 2022 and the NHMRC annual report**

Your bank account details: (Clause 9.1(b))	[#Insert Provider's bank account details (including account name, BSB and account number)] *[#**User Note**: The Provider's account should be with an Australian branch of an established bank, building society or credit union]*
You must use the Funds during the	Funds must be expended by June 2022. Any unspent funds must be advised to the Agency and returned with an

Details	Description	
	following period: (Clause 9.3(a)(iii))	explanation by July 2022.
Budget (Clauses 1.1 and 9.2)	A detailed budget must be submitted on execution of the Agreement. A budget forecast and financial reconciliation must be submitted with each milestone report.	
Assets (Clauses 1.1 and 11)	Asset threshold value: (Clause 1.1)	$NIL (exclusive of GST)
	Other items that are Assets: (Clause 1.1)	***Not applicable***
	Asset obligations: (Clause 11.1(a)(i))	***Not applicable***
	Owner of assets: (Clause 11.2)	***Not applicable***

Milestones
(Clause 1.1 and 5.1(a)(iv))

Number	Milestone	Due date
1	Change management plan developed and submitted to OHMR	Nov 2018
2	Participate in a monthly NSW Health early phase clinical trials HRECs /OHMR change management meetings	Nov 2018- Jun 2018
3	Change management plan executed as evident by new business processes in place and communication with stakeholders Have in place data collection mechanisms for monitoring as agreed with the Agency	30 April 2019
4	Commence ethics review of early phase clinical trial research projects as per NSW Health early phase clinical trial HREC Scheme	April 2019
5	Participate in first HREC Chairs/OHMR quality assurance of	June 2019

Details	Description		
		the 6 monthly meeting	
	6	1st Milestone Report	30 April 2020
	7	2nd Milestone Report	30 April 2021
	8	3rd Milestone Report	30 April 2022

Notified Policies (Clauses 1.1 and 5.2(b))

- Policy Directive PD 2008_030 "HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research"
- NHMRC National Certification Scheme
- National Mutual Acceptance of scientific and ethical review of multi-centre human research

Standards (Clauses 1.1 and 5.2(c))

In accordance with the National Statement on Ethical Conduct in Human Research. and the Australian Code for the Responsible Conduct of Research.

Performance and Outcome Measures (Clauses 1.1 and 5.3)

Below is a list of indicative performance and outcome measures that will be refined and agreed with all NSW early phase clinical trials HRECs once appointed

(a) N days to review applications (defined by days 'on the clock' from submission closing date to initial review decision) (Current target 30- working days with aim to work towards achieving 20-working days benchmark),

(b) N days to review amendments (defined by days 'on the clock' from submission closing date to initial review decision) (Target 10 working days),

(c) Annual number of early phase clinical trial research project applications received and outcome of review,

(d) N of times the delegate from the NSW Local Health Districts and Speciality networks are invited to provide ethical and scientific input during the review process,

(e) Reporting dissenting comments in minutes where a member did not agree with the majority view of the HREC,

(f) Regular attendance at training and development activities: HREC members and Executive officers to undertake training activities to remain fluent in international standards, advances in technology and novel therapies and ethics implications.

(g) Metrics reporting obtained from REGIS on number of early phase clinical trials:
- approval timelines
- number of early phase clinical trials reviewed, approved rejected or referred to CTX
- specific categories of early phase clinical trials received and reviewed.
- triaged to another NSW Health early phase clinical trial HREC

(h) Description of any early phase clinical trials where the NSW Health early phase clinical trial HREC approval has been suspended or withdrawn and the reasons for this action.

(b) the measures will apply annually;

Details	Description
	(c) the Provider's performance will be assessed based in information received through the milestone reporting and intelligence from the sector; and (d) the Provider must report on its provision of the Services against the Performance and Outcome Measures using the milestone reporting templates provided
Subcontracting (Clauses 1.1 and 6.3)	The NSW Health Early Phase Clinical Trial HREC does not require the consent of the Agency when accessing early phase clinical trial expertise.
Additional circumstances requiring immediate notification (Clause 8.2(e))	Immediate notification to the Agency if NHMRC suspends or revokes certification of the HREC. Immediate notification to the Agency if a formal complaint is raised with the Chair of the HREC or the Chief Executive of the host institution regarding the HREC. Immediate notification to the Agency if there are changes in: - HREC member composition or terms of reference; - Sub-committee or affiliated committee composition - HREC Governance and reporting structure
Additional contributions (Clause 9.8)	[#Insert details of any additional monetary or in-kind contributions for the Services (or any other activity that is the same as or similar to the Services) that the Provider has disclosed that it is receiving from another party(s)]
Ownership or licensing of Intellectual Property Rights (Clauses 16.1, 16.2 and 19.4(e)(i))	You
Reporting requirements (Clause 19.4(a)(i))	**Report name** | **Content of report / report requirements** | **Frequency of report** | **Form and method of delivery of report** | **Details of recipient (name, title and email address)**

Details	Description				
	Change management plan	***Plan***	***Once***	***Email to: earlyphase@moh.health.nsw.gov.au***	
	Milestone reports	***Performance indicators and financial acquittal***	***Annual – April 2020-22***	***Email to: earlyphase@moh.health.nsw.gov.au***	***[#Insert]***
Insurance (Clause 20.1)	The Provider must satisfy the following insurance requirements as a condition of funding under the Agreement. The Provider must attach an insurance certificate. • Public liability insurance in the amount of not less than $20million in respect of each and every occurrence and in the aggregate for any one period of cover; • Professional indemnity insurance in the amount of not less than $10million in respect of any one occurrence and in the aggregate for any one period of cover including run-of cover for a period of six years; and • Directors and Officers insurance in the amount of not less than $10millionin respect of each and every occurrence.				
Acknowledgment and publicity (Clause 21.1)	Funding and capability development provided by the Agency must be acknowledged in any publications, advertising and promotional materials must take. HREC Chairs, Executive Officers and members may be required to present or share information on the NSW Health Early Phase Clinical Trial Scheme. All reasonable steps should be taken to respond to such requests.				
Dispute resolution (nominated representatives) (Clause 22.1(d))	Our nominated representative:	Dr Antonio Penna, Executive Director Office for Health and Medical Research			
	Your nominated representative:	[#Insert name of Provider's nominated representative for dispute resolution]			
Dispute resolution (senior representatives) (Clause 22.1(e))	Our senior representative:	Dr Kerry Chant, Deputy Secretary (Population and Public Health) and Chief Health Officer			
	Your senior representative:	[#Insert name of Provider's senior representative for dispute resolution]			

Details	Description
Supplementary Conditions (Clauses 1.1, 2.1(c) and 5.1(a)(vi))	Not applicable
Attachments (Clause 1.1)	1. Milestone reporting template (to be developed) 2. Financial acquittal template (to be developed) 3. Insurance certificate [Attached by the Provider]

EXECUTION

The parties agree that by signing this document they enter into an Agreement comprising of the following documents (in order of precedence):

(a) the Agreement for Funding of Services - Standard Terms;

(b) this Agreement for Funding of Services - Schedule; and

(c) any Attachments.

Executed as an agreement on [#Insert date of execution]

Signed for and on behalf of **Ministry for Health** ABN **[#Insert Agency ABN]** by its duly authorised officer in the presence of:

Signature of witness	Signature of authorised officer
Print name	Print name

[#Note: Select execution clause that is appropriate to the Provider's structure and proposed method of execution and delete the execution clause that does not apply]

Signed by **[#Insert Provider name]** ABN **[#Insert Provider ABN]** by:

Signature of director/company secretary	Signature of director
Print name	Print name

OR

Signed for and on behalf of **[#Insert Provider name]** ABN **[#Insert Provider ABN]** by its duly authorised officer in the presence of:

Signature of witness	Signature of authorised officer
Print name of witness	Name of authorised officer