APPENDIX C – PRO-FORMA REQUEST FOR COSTING AN ELECTION COMMITMENT[1]

Name of policy	The Coalition's Policy to Encourage More Clinical Trials in Australia
Person requesting costing (Prime Minister/Leader of the Opposition/Leader of a minority party):	Prime Minister
Date of public release of policy:	20 May 2016
Date of request to cost the policy:	17 June 2016
Summary of policy (please attach copies of relevant policy documents):	This proposal will provide further funding to assist in the nationalisation of clinical trial standards and develop a streamlined assessment and authorisation process for clinical trials process.
Intention of policy:	This proposal is to remove red tape barriers to conducting clinical trials in Australia by implementing a national system of research ethics approvals and a consistent process for research governance for authorising and conducting clinical trials in Australia.
Certification that this, or a substantially similar costing request, has not been submitted to the Parliamentary Budget Office	This costing has not been previously submitted to the PBO.
Description of policy (please note that, where the request to cost a proposal differs from the announced policy, the costing will be on the basis of information provided in the costing request) **What are the key assumptions that have been made in the policy including:**	
Is the policy part of a package? If yes, list and outline components and interactions with proposed or existing policies.	No
Where relevant, is funding for the policy to be demand driven or a capped amount?	N/A
Will third parties (for instance the States/Territories) have a role in funding or delivering the policy? If yes, is the Australian Government contribution capped, with additional costs to be met by third parties, or is another funding formula envisaged?	The trials are expected to be administered by the National Health and Medical Research Council (NHMRC), however it would require co-operation with state and territory governments, who currently have a number of hospital and state-level based processes.
Are there associated savings, offsets or expenses?	No.

[1] An electronic version of this pro-forma can be found at www.electioncostings.gov.au/templates.

If yes, please provide details.	
Description of policy (please note that, where the request to cost a proposal differs from the announced policy, the costing will be on the basis of information provided in the costing request) **What are the key assumptions that have been made in the policy including:** **(continued)**	
Does the policy relate to a previous budget measure? If yes, which measure?	No.
If the proposal would change an existing measure, are savings expected from the departmental costs of implementing the programme? Will funding/cost require indexation? If yes, list factors used.	This proposal, which seeks to continue and expand an existing terminating program, would provide further funding to assist in the nationalisation of clinical trial standards and develop a streamlined assessment and authorisation process for clinical trials process.
What are the estimated costs each year? Are these provided on a cash or fiscal basis?	The policy would have a negative cash and fiscal impact of $7 million over the FEs. The profile of the cost would be: 2016-17: $2.5 million 2017-18: $2.5 million 2018-19: $1 million 2019-20: $1 million
What assumptions have been made in deriving the expected financial impact in the party costing (please provide information on the data sources used to develop the policy)?	Key costing assumptions include: •Analysis around the national research ethics approvals would consider other Government priorities, including advice from the Australian Medical Research Future Fund Advisory Body. •Funding would be higher in the 2016-17 and 2017-18 to support the acceleration of the program and support negotiations with state and territories, before reducing and stabilising in later years to provide ongoing support for the clinical trial landscape. •Any administrative costs for the Department of Health in relation to overarching policy support would be met from within the funding amount or existing resourcing. The NHMRC would take carriage of the proposal, to expand on an existing terminating program it currently oversees with the same title. •Any amounts which may be provided to state and territory governments would be met from within the funding amount. •Should this policy require additional ASL for the NHMRC in order to administer an ethics approval process, it would be absorbed from within the existing ASL cap of the Health portfolio. This may involve increasing the ASL cap of the NHMRC with an offsetting reduction in the ASL cap of one of more entities within the portfolio.

Has the policy been costed by a third party? If yes, can you provide a copy of this costing and its assumptions?	No
What is the expected community impact of the policy? How many people will be affected by the policy? What is the likely take up? What is the basis for these impact assessments/assumptions?	Clinical trials provide Australians with better and faster access to potentially lifesaving medicines and treatments. The policy will increase the number and value of clinical trials and make it easier to do clinical trials in Australia and attract more international investment by: • making it easier to conduct trials in different states and territories through better regulatory harmonisation and regulatory mutual-recognition; • linking prospective sponsors with research expertise, location and participants; • providing the necessary administrative support to help trials commence more quickly; • adopting new measures to promote patient recruitment; • removing barriers for adolescents and young adult cancer patients in accessing clinical trials for anti-cancer therapies; and • supporting demonstration trials to build Australia's capacity to initiate world-class trials for adolescents and young adult patients that will attract industry partnerships in future trials.
NOTE: it will be up to the professional judgment of the relevant Secretary as to whether these assumptions are adopted in a Treasury or Finance costing of the policy.	

Administration of policy	
Who will administer the policy (for example, Australian Government entity, the States, non-government organisation, etc)?	Department of Health, NHMRC
Should departmental expenses associated with this policy be included in this costing? If no, will the Department be expected to absorb expenses associated with this policy? If yes, please specify the key assumptions, including whether departmental costs are expected with respect to programme management (by policy agencies) and additional transactions/processing (by service delivery agencies).	The costs outlined above are all expected to be Departmental costs associated with implementing the proposal.
Intended date of implementation.	As soon as practicable in the 2016-17 fiscal year.
Intended duration of policy.	Ongoing with a review in 2019-20.
Are there transitional arrangements associated with policy implementation?	No
List major data sources utilised to develop policy (for example, ABS cat. no. 3201.0).	N/A
Are there any other assumptions that need to be considered?	No