

Adolescent/Parent/Guardian Consent Form

Title	The PICOBOO study: The <u>Platform Trial In COVID-19 Vaccine priming and <u>BOO</u>sting</u> , a single blinded, phase IV, adaptive randomised control trial to evaluate the comparative effectiveness of COVID-19 booster vaccines
Short Title	The PICOBOO study
Participant Information Sheet	[insert version number at time of enrolment]
Project Sponsor	Telethon Kids Institute
Coordinating Principal Investigator	Professor Peter Richmond

Please note for the purpose of this consent form, ‘my child’ refers to the child for whom you are legally responsible.

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I understand that my/my child’s participation in this study will allow the researchers and others, as described in the Information for Participants, to have access to my/their medical records, and I agree to this.

I give permission for doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the Telethon Kids Institute concerning my child’s medical information and any treatment for the purposes of this project. I understand that such information will remain confidential.

I give permission for myself/my child to provide blood and saliva samples that will be tested and stored for COVID-19 research (including genetic studies) at participating laboratories as explained to me within the Participant Information Sheet.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to my/my child’s participation in this research project as described and understand that I am free to withdraw myself/my child at any time during the study without affecting my/my child’s future health care.



I understand that my/my child's de-identified data and samples may be used for future research by participating institutions and third party organisation, and I agree to this.

I understand that I will be given a copy of this document to keep.

I understand that some of the staff working on this study are employed by the Vaccine Trials Group (VTG) which is part of the Telethon Kids Institute and are not employed by the Government of Western Australian. These VTG staff are working with the approval of Child and Adolescent Health Service (CAHS) and will follow all the required policies and procedures and safeguard the confidentiality of participant information.

Additional permissions

Do you agree to be contacted about any future research related to COVID-19?

Yes No

My email address is: _____

Declaration by Parent/Guardian – for Parent/Guardian who has read the information (Study participant's Parent or Legally Acceptable Representative (s))	
First & Last Name:	
Name of study participant	
Relationship with study participant	
Signature:	Date:
Study Participant (This section is required for participants considered by the study team to be mature enough to have read and understood the details in this form)	
First & Last Name:	
Signature:	Date:

Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9) a witness to informed consent is required.*

Name of Witness* to Participant's Signature (please print)		_____
Signature	_____	Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. If an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Team

I have given a verbal explanation of the research project; its procedures and risks and I believe that the participant has understood that explanation.

Name of Study team (please print)		_____
Signature	_____	Date _____

Note: All parties signing the consent section must date their own signature.