

LETTER OF CONSENT AND AUTHORISATION FOR SINOVAC COVID-19 VACCINATION UNDER THE PAEDIATRIC SINOVAC AFTER MRNA PROGRAMME

<u>Instructions:</u> This letter is to be completed and signed by the parent/legal guardian of the child/ward, who is giving consent for his/her child/ward to receive the Sinovac COVID-19 vaccination under the Paediatric Sinovac after mRNA Programme. Please provide this letter, duly signed and completed, during your child/ward's vaccination appointment. The letter of consent and authorisation and the SMS invitation from MOH are required for verification. To ensure that vaccination for the child/ward may proceed, the parent/legal guardian must be contactable by the vaccination site staff during his/her child/ward's vaccination appointments should there be any queries. For children aged 12 and below, they must be accompanied by a parent/guardian/proxy during the vaccination appointments.

l,		,, am the
(Nan parent/legal guardian (pleas	,	(NRIC/FIN/Passport Number)
(Name of Child)	, (birth cert/ identit	fication no.)
available for review below mRNA (SAM) Programme	oroviding important infor and the Sinovac COV llar, I understand that th	e Vaccination Information Sheet made rmation on the Paediatric Sinovac afte ID-19 vaccine, which I have read and he use of Sinovac vaccine in persons oproved by HSA.
delete as applicable) dose(s) Paediatric Sinovac after possible risks and side-e screening questions at F	of the Sinovac COVID mRNA Programme. I unifects to the COVID-1 art B of the Paediatr m 1 made available for	y (two/three doses¹) / booster (please 0-19 vaccine, in Singapore, under the understand and agree that there are 19 vaccination. I have reviewed the ric Sinovac after mRNA Programme review below and am satisfied that my accination.
(To be completed if applicable)	also hereby authorise _	
(NRIC/FIN/Passport Number),(g Sinovac COVID-19 vaccin child/ward for the vaccinat the vaccination site staff d be any queries or other ne	uardian/proxy's Local Contact ation appointment on m on appointment. I unde uring my child/ward's va ed to contact me. In the	(Name of guardian/local proxy)), to arrange for my child/ ward's ct No.) y behalf, and to accompany my restand that I must be contactable by accination appointment should there e event that I am uncontactable, I proceed with the vaccination.

¹ as appropriate, and as explained under paragraph 8 of the Programme Information Sheet

PAEDIATRIC SINOVAC AFTER MRNA PROGRAMME PROGRAMME INFORMATION SHEET FOR PARTICIPANTS

1. What is the Paediatric Sinovac After mRNA (SAM) programme? Who is eligible for the programme?

The Paediatric SAM programme is a dedicated public health programme by the Ministry of Health which aims to monitor the safety of administering the Sinovac-CoronaVac vaccine to the respective groups of persons who are unable to receive the mRNA vaccine due to contraindications to the mRNA vaccine:

- (a) Eligible persons aged 3 to under 5 years old, where the Sinovac-CoronaVac vaccine may be administered for the primary series vaccination.
- (b) Eligible persons aged 5 to under 18 years old, where the Sinovac-CoronaVac vaccine may be administered for both the primary series vaccination as well as the booster vaccination.

2. Who is considered to be contraindicated to the mRNA vaccine?

The following groups of persons are considered to be contraindicated to the mRNA vaccine:

- (a) Those who have taken any dose of the mRNA vaccine and have been certified by a doctor to be unable to receive further doses of the mRNA vaccine due to allergy, severe adverse reaction or myocarditis.
- (a) Those who are entirely contraindicated to the mRNA vaccine due to certified allergy to components of the mRNA vaccine, i.e polyethylene glycol, or PEG.

3. What is the Sinovac-CoronaVac vaccine?

The Sinovac-CoronaVac COVID-19 vaccine protects against COVID-19. The vaccine is an inactivated virus COVID-19 vaccine which stimulates the body to produce protection against the actual COVID-19 virus. Persons who have not received any COVID-19 vaccination are recommended to receive three doses of the vaccine as their primary vaccination series. The vaccine is safe for use, but like other vaccines and medications, side effects can happen. These are usually mild and get better in one to three days.

For more information on the Sinovac-CoronaVac vaccine, please refer to the Expert Committee on COVID-19's recommendations on the use of the vaccine, and the Health Sciences Authority's press release on the authorisation of the vaccine. These can be found on MOH's (www.moh.gov.sg) and HSA's (www.hsa.gov.sg) website respectively.

4. Can I / my child receive the Sinovac-Coronavac vaccine under the National Vaccination Programme instead of this dedicated programme?

The use of the Sinovac-CoronaVac vaccine under the National Vaccination Programme (NVP) is only for persons aged 18 and above.

Persons aged 3 to under 18 years old who are medically ineligible to receive the recommended mRNA vaccines under the NVP may receive the Sinovac-CoronaVac vaccine under this dedicated public health programme.

5. As the use of the Sinovac-Coronavac vaccine under the age of 18 is not included in HSA's interim PSAR authorisation, is it safe to administer to them?

Based on the data accrued from clinical trials to-date, the safety profile of Sinovac-CoronaVac is generally consistent with that of other registered vaccines used in immunisation against other diseases. Combined data to-date from the vaccine manufacturer's Phase I / II trials in healthy children and adolescents aged 3 to under 18 years old do not indicate any safety concerns. Some common side effects that vaccine recipients may experience include headache, injection site reaction, muscle pain and general discomfort after vaccination. These symptoms are reactions generally associated with vaccinations and expected as part of the body's natural response to build immunity against COVID-19. These side effects usually resolve on their own within a few days.

This dedicated public health programme will further allow MOH to monitor the safety of administering the Sinovac-CoronaVac vaccine to persons aged 3 to under 18 years old.

6. Will I / my child have to pay for the Sinovac-Coronavac vaccine under this programme?

No. The Sinovac-CoronaVac vaccine will be administered at no charge to persons who are eligible for the Paediatric SAM programme.

7. Where can I / my child receive the vaccination under the Paediatric SAM programme? How many doses of the vaccine are needed? What can be expected at the Vaccination Centre?

<u>Primary vaccination series.</u> Eligible persons aged 3 to under 18 years old who opt to participate in the programme will receive a two- or three-dose primary series (see table below) of the Sinovac-Coronavac vaccine at either KK Women's and Children's Hospital (KKH) or National University Hospital (NUH).

Category	Number of doses and interval between doses
Persons who have previously taken one	A total of two doses of the Sinovac-Coronavac vaccine will be
dose of the mRNA vaccine and are medically ineligible for / have been advised	administered.
against taking the second dose of the mRNA vaccine due to allergy, severe adverse reaction or myocarditis	Dose 1: Recommended at 8 weeks after the mRNA vaccine Dose 2: Recommended at 8 weeks following Dose 1
Persons who are entirely contraindicated to the mRNA vaccine and have not taken any dose of the mRNA vaccine	A total of <u>three doses</u> of the Sinovac-Coronavac vaccine will be administered.
	Dose 2: Recommended at 8 weeks following Dose 1 Dose 3: Recommended 3 months (90 days) following Dose 2

<u>Booster dose</u>. Eligible persons aged 5 to under 18 years old who opt to participate in the programme will receive one dose of the Sinovac-Coronavac vaccine at the stipulated interval following their primary vaccination series (see table below) at KKH or NUH.

Category according to primary vaccination series	Number of Sinovac booster doses and interval between doses				
Persons who have previously taken one dose of the mRNA vaccine and thereafter received two doses of Sinovac OR	One dose of Sinovac is recommended approximately <u>3 months</u> after the final vaccine dose of their primary vaccination series.				
Persons who were entirely contraindicated to the mRNA vaccine and received three doses of Sinovac					
Persons who have completed both doses of the mRNA vaccine but are contraindicated to future doses of the mRNA vaccine	One dose of Sinovac is recommended approximately <u>5 months</u> after the final vaccine dose of their primary vaccination series.				

<u>Post-vaccination monitoring</u>. Participants will be monitored closely for post-vaccination side effects on-site (for 30 minutes after any dose of the primary series, and 15 minutes after a booster dose) and will also be asked to fill out a short online survey using a FormSG QR code immediately after each dose, as well as in the days following vaccination.

8. Will I / my child be eligible for the Vaccine Injury Financial Assistance Programme (VIFAP) under this programme?

As part of the Paediatric SAM programme, participants are eligible for the SAM Financial Assistance Scheme (SAMFAS), which provides goodwill financial assistance should they experience a serious side effect or adverse event after receiving the Sinovac-Coronavac vaccine, that requires hospitalisation for treatment or results in persistent disability which is assessed to be likely to be related to the vaccination.

9. Can you provide an overview of the SAM Financial Assistance Scheme (SAMFAS)?

The amount of financial assistance provided is fixed and dependent on the severity of the serious side effect or adverse event, as indicated in the table below. Pay-out will be based on the highest quantum eligible, and persons will be eligible for one pay-out only e.g. only \$225,000 for death and permanent severe disability, regardless of hospital stay or treatment.

	Type of Serious Side Effect or Adverse Event	One-time Pay-out Amount
1	Results in death or permanent severe disability	\$225,000
2	Requires admission to High Dependency or Intensive Care, with	\$10,000
	subsequent recovery	
3	Inpatient hospitalisation of any duration (excluding visits to the	\$2,000
	Emergency Department without subsequent inpatient admission).	ļ

Please note that this is a goodwill financial assistance as part of the programme that is independent of existing healthcare financing and insurance schemes. It is not meant to reimburse medical costs associated with the serious side effect or adverse event. Individuals who experience side effects after the Sinovac-Coronavac vaccination can continue to receive support through applicable healthcare financing schemes, such as MediShield Life and subsidies at our public healthcare institutions. Persons with private insurance may wish to check with their insurance provider on their coverage details.

10. How do I / my child apply for SAMFAS?

You may apply for financial assistance under the Paediatric SAM programme by submitting an application online at https://go.gov.sg/samfas-covid.

All applications must be supported by the assessment of a medical doctor. As part of your submission, you are required to provide the "Request for Medical Information" form which must be completed by your primary attending doctor. You may download the "Request for Medical Information" form at https://go.gov.sg/samfas-request-for-med-info-form. Please request your doctor to complete it and return the form to you for your application to MOH. Applications will not be processed in the absence of a completed "Request for Medical Information" form.

11. How can I / my child receive the Sinovac-Coronavac vaccine under this programme?

Eligible persons will receive an SMS from MOH, inviting them to participate in the Paediatric SAM programme. Please follow the instructions in the SMS. You / your child must provide the necessary consent and identification documents in order for your child to participate in the programme.

12. May I receive the Sinovac-Coronavac vaccine at another location?

No. Participants in the Paediatric SAM programme may only receive the Sinovac-Coronavac vaccine at either KKH or NUH.

13. Why do I have to sign an informed consent form? Is the Paediatric SAM programme a research study?

A signed informed consent form is required to ensure that you have considered and discussed the risks and benefits of receiving the Sinovac-Coronavac vaccine outside of the Health Sciences Authority's (HSA) Pandemic Special Access Route (PSAR) authorisation and indications.

The Paediatric SAM programme is a public health programme approved and funded by MOH, to closely monitor the health of persons who are unable to complete their mRNA COVID-19 vaccination, by providing a non-mRNA option safely. Any data collected will be anonymised and shared in group form and used for the purposes of improving public health policy or to educate the public about vaccinations.

14. How will I be monitored for post-vaccination side effects?

Please fill in this short online survey form, with your symptoms (even if none) as part of vaccine safety monitoring by scanning the QR codes below. This will help us take better care of future participants.

Time After Vaccination	Day 0	Day 1	Day 3	Day 7
	(right after)	(24 hours after)	(72 hours after)	(1 week later)
Scan QR Code				





VACCINATION INFORMATION SHEET SINOVAC COVID-19 VACCINE (CORONAVAC) FOR PARTICIPANTS IN THE PAEDIATRIC SINOVAC AFTER MRNA (SAM) PROGRAMME

This vaccine has been granted authorisation under the Pandemic Special Access Route (PSAR) by the Health Sciences Authority (HSA) for use in Singapore in persons aged 18 and older under the direction of the Ministry of Health. Persons who are aged 18 and older may receive the vaccine under the National Vaccination Programme.

You / your child are receiving this information sheet as you / your child are eligible to receive the Sinovac COVID-19 vaccine (CoronaVac) under the Paediatric SAM Programme, a dedicated public health programme by the Ministry of Health.

The Paediatric SAM Programme aims to monitor the safety of administering the Sinovac COVID-19 vaccine (CoronaVac) to the respective groups of persons who are unable to receive the mRNA vaccine due to contraindications to the mRNA vaccine:

- (a) Eligible persons aged 3 to under 5 years old, where the Sinovac COVID-19 vaccine (CoronaVac) may be administered for the primary series vaccination.
- (b) Eligible persons aged 5 to under 18 years old, where the Sinovac COVID-19 vaccine (CoronaVac) vaccine may be administered for both the primary series vaccination as well as the booster vaccination.

Please read this information carefully. Consult your doctor or clinic if you have questions.

15. What is COVID-19?

COVID-19 is a respiratory illness that can range from mild to severe disease. Spread is mainly through droplets, airborne particles, or touching contaminated surfaces. Symptoms appear 2 to 14 days after exposure, and can include fever, cough, shortness of breath, sore throat, runny nose or loss of smell or taste. Complications can include respiratory failure, heart attacks, blood clots and other long-term problems.

16. What is the Sinovac COVID-19 vaccine (CoronaVac)?

The Sinovac COVID-19 vaccine (CoronaVac) protects against COVID-19. The vaccine is an inactivated virus COVID-19 vaccine which stimulates the body to produce protection against the actual COVID-19 virus.

The vaccine consists of 3 doses. The second dose is given 8 weeks after the first dose, while the third dose is given 3 months after the second dose. The vaccine is safe for use, but like other vaccines and medications, side effects can happen. These are usually mild and get better in 1 to 3 days.

For more information on the Sinovac COVID-19 vaccine (CoronaVac), please refer to the Expert Committee on COVID-19's recommendations on the use of the vaccine, and the Health Sciences Authority's press release on the authorisation of the vaccine. These can be found on MOH's (www.moh.gov.sg) and HSA's (www.hsa.gov.sg) website respectively.

17. Who should get the vaccine? Who should not get the vaccine?

You should get this vaccine to be protected against COVID-19, if you are unable to complete vaccination with the mRNA vaccines (Pfizer-BioNTech / Comirnaty or Moderna) due to an allergic reaction to the mRNA vaccine or its components.

You should **NOT** get this vaccine if you had an allergic reaction (including anaphylaxis) to a prior dose of this vaccine or to any ingredients in this vaccine (see Section 5).

Tell your doctor or nurse before getting this vaccine if you:

- had a fever in the past 24 hours
- have active cancer treatment, organ/stem cell transplantation, or are immunocompromised
- have a low platelet count, bleeding disorder, or taking blood thinning medications
- are pregnant, or think you may be pregnant

You likely can still receive the vaccine, but the doctor or nurse may provide additional advice.

18. How is the Sinovac COVID-19 vaccine (CoronaVac) given?

This vaccine is given as an injection into the muscle of your upper arm.

19. What are the ingredients in the Sinovac COVID-19 Vaccine (CoronaVac)?

The Sinovac COVID-19 vaccine (CoronaVac) includes the following ingredients: Inactivated SARS-CoV-2 Virus (CZ02 strain); aluminium hydroxide; disodium hydrogren phosphate dodecahydrate; sodium dihydrogen phosphate monohydrate; sodium chloride.

20. What are the possible side effects? How do I manage the side effects?

Like other vaccines and medications, side effects can happen. Most side effects are mild or moderate, and usually get better within a few days. The table below lists some common side effects that have been reported with this vaccine, and how to manage them.

Side Effects	How to Manage					
Pain, redness, swelling at the injection site	Those with fever are advised to self-isolate					
Fever, chills	at home until the fever subsides. Paracetamol 10mg/kg/dose every 6 hours.					
Headache, muscle pain, joint pain						
Tiredness (Fatigue)	Rest					

- See a doctor if side effects persist or get worse.
- See a doctor to get tested for COVID-19 if you develop cough, sore throat or runny nose, since you don't develop full protection until at least 2 weeks after completing the second dose.
- Rarely, this vaccine may cause Bell's palsy, which is a temporary paralysis on one side of the face.
 This is a separate condition from a stroke. If you experience weakness on one side of your face, seek medical attention immediately.
- Very rarely, this vaccine may cause a severe allergic reaction or anaphylaxis. Symptoms include
 difficulty breathing, swelling of your face/throat/eyes/lips, fast heartbeat, dizziness/weakness, or
 rash. If you experience these, seek medical attention immediately. Call 995 or go to the nearest
 A&E immediately.
- If you experience side effects after vaccination which are not listed above, please consult your doctor.

21. Other Advice

Advice for different groups of vaccine recipients:

- If you are on blood thinning medicines, press firmly on the injection site for 5 minutes.
- If you are pregnant, you may wish to consult your obstetrician to discuss benefits and risks.
- If you are on active cancer treatment, recent organ/stem cell transplantation or are on aggressive immunotherapy, please consult your specialist to discuss if you can get this vaccine.

Before vaccination:

- Continue to take your medications as usual, and do not stop them just for the vaccination.
- Avoid dehydration or skipping meals, to reduce risk of fainting after vaccination.
- If you have a fever or are acutely ill, you should re-schedule your vaccination.

After vaccination:

It is advisable to avoid the following after vaccination, to reduce the risk of adverse effects:



- Avoid drinking alcohol for 12-24 hours after getting vaccinated
- Avoid taking non-steroidal anti-inflammatory drugs (NSAIDs) for pain or fever after vaccination. (NSAIDs include medications like ibuprofen, ketoprofen, naproxen, and diclofenac.)

22. How do I report side effects?

If you experience severe or unusual side effects, see your doctor, who will be able to advise you and report the side effects to HSA. You may also report side effects directly to HSA on a form by scanning this **QR code**.

23. What is the Pandemic Special Access Route (PSAR)?

PSAR is an authorisation process by HSA to facilitate early access to vaccines and medicines during a pandemic, such as COVID-19.

The content of this information sheet was updated on 10 Oct 22. For the latest COVID-19 vaccine consumer information, please refer to the HSA website at https://www.hsa.gov.sg/covid-19-information-and-advisories

PAEDIATRIC SINOVAC AFTER mRNA PROGRAMME – VACCINATION SCREENING FORM (FORM 1) TO BE COMPLETED BY PATIENT/PARENT/LEGAL GUARDIAN (please approach our staff if you need help)

PART A: PERSONAL PARTICU											istration
NAME of person receiving vaccination (BI	LOCK LETTERS):		NRIC	No./Fo	oreigi	n Ider	ntific	ation	No.(FI	N):	
Gender: Date of Birth (dd/mm/yyyy):	\ge:	Ethnic Grou	ıp:		Res	sident	tial S	tatus:			
□ Male □ Female		☐ Chinese ☐ Malay	3 1						•		
Address*:					Han	ndpho	ne N	lumbe	er:		
					Em	ail Ad	Idros	·c*-			
	Postal Code	e:				an Au	idi Co				
PART B: MEDICAL INFORMATION											Waiting Area
PART B1: FEVER									NO		YES
Have you had a fever (Temperature	≥ 37.5°C) in the past	24 hours?									
PART B2: ADVERSE EVENTS TO VAC	CINES								NO		YES
Do you have any known allergies to	the SINOVAC vaccine	e, or its con	npone	nts, o	or ot	her					
inactivated vaccines?											
Have you taken any dose of the mR	NA COVID-19 vaccine	?									
If yes, when did you receive your fir	st dose of mRNA CO\	/ID-19 vaco	cine?								
• Date:											
Which vaccine did you recei	ive?								Pfize	er	☐ Moderna
What was your reaction to to	the mRNA COVID-19	vaccine?									
 Anaphylaxis: severe 	reaction with two or	more of tl	he foll	owing	g: (a)) hive	es				
or face/eyelid/lip/tl	hroat swelling, (b) diff	ficulty brea	athing,	, (c) di	izzin	ess					
 Rash or hives or fac 	e/eyelid/lip swelling										
 Myocarditis / perica 	arditis										
 Other side effects: 	List										
PART B3: SPECIAL SITUATIONS (CAI	N STILL VACCINATE)								NO		YES
Have you ever had anaphylaxis to m	nedications, insect sti	ngs, food o	r unkr	nown	trigg	gers?)				
(For females) Are you pregnant or s	uspect that you are p	regnant (la	ate me	enstru	al pe	eriod	1)?				
Are you currently taking these medi	ications or have these	e medical c	onditi	ons?							
 Blood-thinning medications (e 	e.g. warfarin, apixabaı	n, rivaroxal	ban et	c)							
Bleeding disorder or low plate	elets										
On cancer treatment (immuno	otherapy / chemothe	rapy / radio	othera	py in	the	past	3				
months OR planned in the nex	kt 2 months)#										
Recent transplant in the past 3	3 months#										
 Aggressive immunotherapy fo 	r non-cancer condition	ons (e.g. rit	uxima	b etc)) #						
PART C: PATIENT DECLARATION AN	ID CONSENT										
I declare that the information I have	e given is true and cor	mplete to t	he be	st of r	ny k	now	ledg	ge.			
I understand that the use of SINOVA	•		_								
HSA. I have further been informed										VOV	AC COVID-19
vaccination, and I wish to receive / have my child/ward receive the SINOVAC COVID-19 vaccination.											
Du concenting to participate in this Dandistric CAM program I agree to receive / baye my shild/ward receive the											
By consenting to participate in this Paediatric SAM program, I agree to receive / have my child/ward receive the SINOVAC vaccine, to complete the survey monitoring for post-vaccination side effects, and to provide MOH access to											
my medical records.											
☐ I AGREE to receive / that my child/ward may receive the ☐ I DO NOT wish to receive / have my child/ward receive											
SINOVAC COVID-19 vaccination; OR the SINOVAC COVID-19** vaccine											
THE SITE OF THE COVID 15 VACCING											
		I									

^{*} Fields not required if names are submitted via nominal roll, appointment booking system and healthcare workers under the self-vaccination

exercise.

** If patient does not wish to receive COVID-19 vaccine, there is no need to complete FORM 2. # Memo from treating specialist is required to proceed with vaccination.

PAEDIATRIC SINOVAC AFTER mRNA PROGRAMME - VACCINATION SCREENING FORM (FORM 2) TO BE COMPLETED BY DOCTOR OR NURSE AT THE VACCINATION SITE

PART D: CLINICAL SAFETY REVIEW OF PATIENTS								
PART D1: CONTRAINDICA	NO	YES						
IF YES → DO NOT VACCII								
 Anaphylaxis or alle 								
•	her inactivated vaccines							
PART D2: PRECAUTIONS		TON	NO	YES				
IF YES → DO NOT VACCII			_	_				
		le for after fever resolved						
PART D3: SPECIAL SITUA			N/A	YES				
IF YES to being anti-coago	•		_					
-	mly on injection site for 5	minutes						
IF YES to being pregnant:								
•	ishes to discuss with obst							
	•	been assessed by treating specialist						
	nt (immunotherapy / che or planned in the next 2	motherapy / radiotherapy) less months						
 Recent transplant i 	in the past 3 months							
 Aggressive immune 	otherapy for non-cancer o	conditions (e.g. rituximab, etc.)						
IF YES to history of anaph	nylaxis >							
Ensure post-vaccing								
CLINICAL ASSESSMENT:			Form Cor	npleted by				
	verse effects discussed; qu							
	ormed consent has been s	signed						
VACCINATE?								
☐ YES → PROCEED TO								
□ NO		NO MACCINIATION						
_	has contraindications \rightarrow I		No control (Six and control (Six and control)					
☐ Fever → RESCHE	EDULE vaccination when f	ever has resolved	Name / Signature / Date					
PART E: VACCINATION R	ECORD							
COVID-19 vaccine given:	Injection site:	Vaccine Brand:	Batch numbe	r:				
☐ #1 Date:	☐ Left deltoid	☐ Pfizer-BioNTech/ Comirnaty						
☐ #2 Date:	☐ Right deltoid☐ Other	☐ Moderna ☐ Sinovac						
☐ #3 Date:	Bottle number							
☐ #4 Date:	(if applicable):							
Place of Vaccination		Vaccinated By:						
		Name (stamp) / Si	gnature / Date					
PART F: OBSERVATION 8	DISCHARGE							
☐ Vaccine card & vaccine	e information sheet (VIS)	given	Time of vacci	nation:				
☐ Observe patient for 30) min after vaccination (fo	r syncope, anaphylaxis etc)						
☐ If allergic symptoms do	evelop, observe until stab	le or refer to ED						
Remarks by doctor (If tre	atment required):	Assessed by:						
		Name (stamp) / Si	gnature / Date					