



**INFORMED CONSENT FORM (ELECTRONIC, ONLINE)**

The participant will have read the Participant Information Sheet (PIS) online and will then be asked a series of questions. They will need to answer all with TRUE or FALSE.

All questions to be answered correctly in order to access final e-consent sign off.

CONSENT FORM (SISONKE STUDY) (VAC31518COV30XX)					
Field Number	Field	Field Type	Acquisition	Logic check	Notes
Choose either true or false for each of the following statements to demonstrate that you have understood and give consent to take part in this trial. You must answer each question correctly to proceed.					
	Date	Date DD-MON-YYYY	Automatic		Set to 'today'
	I have read and understood the participant information sheet (PIS) for the Sisonke Study either online at <a href="http://sisonkestudy.samrc.ac.za/">http://sisonkestudy.samrc.ac.za/</a> I have considered the information and my questions have been answered.	Radio button True   False	Manual	Mandatory  True	<b>If False answer the following text will appear:</b> You must read and ensure you understand the participant information sheet before you can offer informed consent to this study.
	I allow the research team conducting the study to access my medical records to assess adverse events and infections for up to 2 years.	Radio button  True   False	Manual	Mandatory  False	<b>If False answer the following text will appear:</b> It is important the study team are allowed access to your medical records if you become ill from COVID-19 or develop a side effect. This will help us understand how effective and safe the vaccine is.

	I have not received an additional vaccine outside the Sisonke study such as Pfizer, Astra Zeneca etc.	True/False	Manual	Mandatory True	<b>If False answer:</b> it may be unsafe to receive another vaccine and therefore you are not eligible to continue.
	Regulatory authorities will be allowed access to my medical and study records. They will maintain confidentiality.	Radio button  True   False	Manual	Mandatory  True	<b>If False answer the following text will appear:</b> It is important that regulatory authorities have access to your medical records related to this study (if needed) to ensure that the study is being carried out to the highest standards.
	I will allow my personal details to be used to obtain medical information from my healthcare provider, the department of health and national healthcare registries if I have an adverse effect or a break through infection.	Radio button  True   False	Manual	Mandatory  True	<b>If False answer the following text will appear:</b> It is important that the study team may access your medical records to check vaccine safety and effectiveness.
	I consent to the disclosure of relevant information and medical records by staff at that hospital, if I am admitted to hospital	Radio button  True   False	Manual	Mandatory  True	<b>If False answer the following text will appear:</b> The study team may need to access your medical records in order to check vaccine safety and effectiveness.
	I understand that the information collected in this study may be shared with collaborating Sisonke researchers . The information shared will not include my name or contact details. This will be related to COVID-19 and vaccines.	Radio button  True   False	Manual	Mandatory  True	<b>If False answer the following text will appear:</b> It is important for researchers to learn as much as possible about COVID-19. All research studies

					will be ethically approved. We will keep all information about you safe and secure. All other researchers must keep your information safe.
	I will be free to withdraw from the trial at any time, without giving any reason and without my medical care or legal rights being affected.	Radio button  True   False	Manual	Mandatory  True	<b>If False answer the following text will appear:</b> You will be free to withdraw from the trial at any time, without giving any reason and without your medical care or legal rights being affected.
	If I choose to withdraw, I understand that any new results reported after my withdrawal will not use my data.	Radio button  True   False	Manual	Mandatory  True	<b>If False answer the following text will appear:</b> If you take part in this study then later withdraw, any new results reported after your withdrawal will not include your data.
	I agree to take part in the Sisonke study, including any necessary follow-up. I certify that all the information in the page above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.	Action button  Submit	Manual	Mandatory	