PARTICIPANT INFORMATION AND INFORMED CONSENT FORM

Protocol Name: TASK-008 BCG-CORONA

Protocol Title: Reducing morbidity and mortality in health care workers exposed to SARS-CoV-2 by enhancing non-specific immune responses through Bacillus Calmette-Guérin vaccination, a randomized controlled trial.

Participant Initials:_____ Participant Number:_____

Dear Participant

Please read this information sheet before you agree to take part. Bacille Calmette-Guérin (BCG) is a vaccine against tuberculosis (TB) registered in South Africa. It has protective non-specific effects against other respiratory tract infections. In clinical trials, the BCG vaccine has been shown to train your immune system which may allow it to react better to infections from bacteria and viruses.

What is the study about? We want to test if this BCG vaccine is able to help your body respond faster to infection with SARS-CoV-2, and hopefully prevent you from becoming very ill. There is currently no prevention or treatment for SARS-CoV2 available in South Africa or anywhere else in the world. Half of the participants on the study will get the vaccine, and half will get an injection with a saltwater solution that has no effect (placebo). This is because we don't know if the vaccine will work against the virus. If you take part, you will have an injection in your arm with either the BCG vaccine, or a placebo. It is important to note that you will be randomly (like flipping a coin) assigned 1:1 to either receive BCG vaccine or the placebo. At least 500 participants will be recruited from sites based in Cape Town, South Africa.

Is this safe? **The study has been approved by Pharma Ethics Independent Research Ethics Committee and by the South African Health Products Regulatory Authority (SAHPRA) for compliance with medical and the South African National Health Ethics Council guidelines and standards. In addition, the study will be conducted according to the 2013 Declaration of Helsinki and guidelines for good clinical practice (GCP) in the conduct of clinical trials that involves the participation of human subjects in South Africa, second edition, 2006 which protects your rights and guides the study staff in research involving human participants.** BCG vaccination is a safe and frequently performed procedure.

What are the risks of BCG vaccine or placebo? The most common side effects of BCG vaccination are headache, fever, discomfort, swelling or scarring at the injection site, nausea and vomiting. Rare but severe reactions may include an abscess at the site of injection, or a severe allergic reaction. Side effects may be more common in those that have been vaccinated with BCG before. BCG is a live attenuated vaccine. Rarely a participant, more so in those with compromised immune systems, may develop an abscess or BCG disease for which you will need treatment. BCG disease means the live bacteria called M.bovis can cause infection which is similar to TB. This may present as enlarged lymph nodes, infection in the lungs, bone or other areas of the body and is treatable. Injection with the placebo may cause discomfort, bruising and swelling at the injection site.

It is not safe to receive the BCG vaccine if you are HIV positive or pregnant. You will have your medical history reviewed and undergo an HIV test and pregnancy test (if female) before the injection to ensure it is safe to do so.

What will happen to me in the study? You will sign this document in which you indicate you are voluntarily consenting to be part of the trial. You will be offered a copy of the signed informed consents to take home. We will collect information about you such as your date of birth, gender and ethnicity, and your medical history. If you don't know your HIV status you will undergo a HIV test after counseling and a separate consent process. This is required to participate as BCG is not safe in HIV positive individuals. If you are female and of childbearing potential, we will test a urine sample for pregnancy as the safety of BCG in pregnancy is unknown. We will test your blood pressure, heart rate, respiratory rate, temperature, body weight and height.

Then we will review all information and decide if you can take part. If yes, you will have your blood drawn (up to 20ml) for a TB infection and SARS-CoV-2 serology test and will then receive the vaccination. We will thereafter contact you by phone, text message or email, approximately weekly to monthly until 1 year. We will want to know how you are doing and will take you through a brief questionnaire. For safety and data integrity you should inform us immediately if you are planning to take part in another trial. We will ask to see you for a finger prick or blood draw (up to 20ml each) to find out if you have TB and/or SARS-CoV-2 infection at week 26 and week 52. There may also be a test at week 10. If we are unable to reach you to conduct a visit, we may contact your next-of-kin or employer to find out how you are doing. If you have been hospitalized we will contact your healthcare provider to obtain your medical records. By signing this consent form, you also give us permission to access health records and databases to find out what happened to you and to access your laboratory results.

Procedure	**Screening**	**Follow Up**	
Visit	Day 1	WK 1-51	WK 10, 26, 52 or withdrawal
Consent, demographics	X		
Medical and treatment history	X		
Vital signs, HIV test and pregnancy test	X		
Eligibility check	X		
BCG or placebo	X		
Symptoms and questionnaire	X	X	X
Blood test(s)	X		X

Do I have to agree to be on the study? No, this is completely voluntary. If you decide not to take part or to withdraw from the study, please contact us immediately. If you should withdraw from the study, no new information will be collected for the study database unless you specifically consent to that. However, the law does require that any side affects you may suffer are documented and reported. To complete the study findings, your long-term health status may also be recorded (unless you object). This will not change your access to other medical care. You will be informed if information becomes available that may affect your decision to participate.

Will I benefit from the study? There is a chance that if you become infected with SARS-CoV-2, you may not get as sick because of the vaccine, but we cannot guarantee this. If you receive the placebo you will not gain any direct benefit from participating in this study, but your participation may help prove the potential benefit of BCG vaccination in preventing poor COVID-19 outcomes. You will not be paid to participate in this study. Any study-related costs will be paid for by the sponsor. Neither you, your medical scheme nor your healthcare provider will be responsible for these expenses.

Are there other choices for treatment? No, not at this time.

What will happen if I get hurt in the study? If you are injured due to no fault of your own as a result of your participation on the study, such as a side effect of the BCG vaccine or injection, you will be covered by insurance taken out with Santam Limited (Reg. 1918/001680/06) (VAT no. 4440102095) which has been taken out by the sponsor of the study in case you get injured. The insurer will pay for all reasonable medical costs required to treat your bodily injury, in accordance with the SA Good Clinical Practice Guidelines (2006 or latest version), which are based on the Association of the British Pharmaceutical Industry Guidelines. You may request a copy of these guidelines from the study doctor. If you have been negligent or withheld information which may have affected your participation on this study, you may be paid less or not at all. If you belong to a private medical scheme, you should inform them that you are participating in a research study.

What will happen to my personal information, how will you protect my confidentiality?
You have the right to control the use and disclosure of your personal information. Basic personal information will be recorded including your name, contact details, gender, height, weight, etc., as well as information on your medical history, and clinical data collected about your participation in the study. The following people may also access these records:

- Study monitors, auditors and contractors who may work for the Sponsor or its affiliates/authorized representatives, who check that the study is being performed correctly and that the information collected about you is accurate.
- Research Ethics Committees that approved this study and ensures that your rights and well-being are safeguarded.
- National and international regulatory authorities involved in keeping research safe for participants.

All personnel accessing your records are required to respect your confidentiality at all times. Representatives from government agencies such as the South African Health Products Regulatory Authority (SAPHRA), the National Health Research Ethics Council (NHREC) and Pharma-Ethics Research Ethics Committee, the Sponsor and or the sponsor's authorized representatives may need access to your original medical records and study records to confirm that the study data collected about you is correct and relates to you. All records identifying you will be kept confidential, and to the extent permitted by applicable laws and regulations, will not be made publicly available. No personal information will be included in the study data that will be forwarded to the sponsor or sponsor representatives. You will be identified by a coded number in any reports of publications produced from this study (study data). By signing this document, you are authorizing such access.

Under data protection law "Protection of Personal Information Act 2013" your study site and the sponsor will be jointly responsible as 'controllers' to ensure that your information is safeguarded. Your data might be transferred to a country that may not have the same level or personal data protection as South Africa. If your data is transferred outside South Africa the sponsor is responsible for protecting your data. The sponsor or representatives may use the study data sent to them for the following:

- To see if the study medication works and is safe.
- To compare the study medication to other medications.
- For other activities relating to the study medication.

You have the right to ask the study doctor about the data being collected on you and to see your personal health information and, if applicable, ask for corrections. However, in

order to protect the scientific integrity of the study, the treatment you received in this study needs to remain unknown until the study data is analyzed.

What will happen to my blood sample? They will be analyzed in SU-IRG laboratory in South Africa. The results of your testing can be made available to you. Your samples will be destroyed after testing is completed. If you withdraw from the study, you may also request to have your samples destroyed.

Who is in charge of the study? The study sponsor is TASK, a non-profit company based in Cape Town who have done research on TB medicines for 15 years.

What are my rights as a research participant? We will tell you about new research information that may affect your health, welfare, or willingness to stay in this study. We will share a summary of the results with you when they are ready.

Whom can I contact if something worries me?

If you have any questions about this trial, you can discuss them with Dr Caryn Upton, contact number 021 510 2209 or the study nurses and doctors. In case of an emergency, you can call, send an SMS or a WhatsApp message to the doctor on call on **071 405 9474**.

If you want any information regarding your rights as a research participant, or have questions or complaints regarding this research study, you may contact the ethics committee, which is an independent committee established to help protect the rights of research participants. If you have questions about this trial after speaking to your doctor and the ethics committee, you should write to the ethics committee or SAHPRA at:

Pharma-Ethics Independent Research Ethics Committee
123 Amcor Road
Lyttelton Manor
Pretoria 0157
Tel no: 012 664 8690
Fax: (0)12 664 7860
e-mail: marzelle@pharma-ethics.co.za

Acting Chief Executive Officer
SAHPRA
Department of Health
Private Bag X828 Pretoria 0001
Tel: 0128427582/3 or 0788020781
Email: portia.nkambule@sahpra.org.za

Consent statement

By signing below, I agree that:

	Initial Blocks
• I have read or had read to me the information on this sheet	
• I understand that this trial is investigational and what it means.	
• I under the purpose, treatment and procedures of this trial	
• I understand my responsibilities as a trial participant.	
• I understand that participation is voluntary and that I can withdraw at any time, without it affecting my ongoing care.	
• I understand the possible risks, harm and inconvenience.	
• For women: I am not pregnant	
• I have been informed of the expected benefits of the trial.	
• I have been informed that there is no alternative treatment.	
• I have been informed of the compensation and treatment that would be available to me in the event of a trial-related injury.	
• I have been informed that I will not be paid for participating	
• I have had sufficient time to discuss this study with others, ask questions and they were answered to my satisfaction.	

• I am aware that the results of the trial, including personal details about me and my health information may be reasonably disclosed to the sponsor, regulatory authorities and research ethics committees, if required by law.	
• I will be offered a signed and dated copy of this consent form.	
• I agree that if I am hospitalized, you may access my medical records, results and health information including those in electronic databases.	
• I agree to participate in this trial.	

PARTICIPANT INFORMED CONSENT FORM

_____
Printed full name and surname of participant

_____
Signature/mark/thumbprint of participant Date and Time

_____
*Printed name of designee conducting the consent

_____
*Signature of designee conducting the consent Date and Time

I, _____(Insert name of investigator) hereby confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

_____
Signature of investigator Date and Time

By signing below, I verify that the above participant gave verbal informed consent. The participant has been informed about and understands the risks and the benefits of the study and agrees to participation, without coercion, undue influence or inappropriate incentives.

_____
*Printed full name and surname of witness (only if applicable)

_____
*Signature of witness (only if applicable) Date and Time