

# **COVID-19 Vaccination Detoxication in Low Density Lipoprotein Cholesterol**

**Protocol Number: SARSCoVVAXDetox**

**National Clinical Trial (NCT) Identified Number: NCT05839236**

**Principal Investigator: Yang I. Pachankis**

**<IND/IDE> Sponsor: Yang I. Pachankis**

**Informed Consent Form**

**<1 May 2023>**

# **INFORMED CONSENT**

Principal Investigator: Yang I. Pachankis

NCT Number: NCT05839236

## **INTRODUCTION**

The conditions of the participant from the interventional trial NCT05711810 has stabilized with angiotensin receptor neprilysin inhibitor in the follow-up studies, and the current study renews the previous purposes of the study designs. The participant's historic data days after the second vaccine shot provided valuable evidence to the study design, and the Principle Investigator (PI) evaluates that there is the possibility to detox the active and hibernating viral proteins from the original participant. Therefore, the informed consent is being renewed from the pilot studies.

## **PURPOSE OF THE RESEARCH**

Vaccine poisoning starts from the sebaceous glands, and sebaceous immunobiology is a recent concept. The research seeks to obtain empirical evidence and primary data from the clinical trial for inference on sebaceous immunobiology and the roles and functions of chromatophores. The neurodivergent symptomatic emergence of the participant in the pilot studies has provided a window for the behavioral observations for the inference with the effects in the detoxication (cure) process.

## **TYPE OF RESEARCH INTERVENTION**

The clinical trial is both interventional and observational. The interventional element of the trial is constituted of the clinical curing experiment from the PI's prior analysis, and the observational element of the trial is constituted of the symptomatic disappearance from the curing process.

## **PARTICIPANT SELECTION**

The participation is on a voluntary basis, and the participant is currently selected with regard to the prior participation. The terms from the prior participation remain the same.

## **VOLUNTARY PARTICIPATION**

You have full autonomy in the participation, or withdrawal of consent thereof in the participation process. The PI takes medical responsibilities on the participants, and the participants agree to report to the PI any medical or symptomatic situations during the participation process. The PI will explain any questions or doubt during the participation process, or thereafter with medical situations related to the participation, regardless of possible withdrawals during the participation. If in doubt, or distrust of the treatment, you have the full autonomy in withdrawing from the participation. Unless there is concrete proof that the treatment has direct adverse impact on the participants, you agree that the PI will not be held legally liable for your suspected reasons from the withdrawal of consent. You understand that, due to the pathogen's potentials in neurological infections, you might experience negative emotional turbulences during the treatment process. The PI will offer psychological service to you during the participation, and the service records will belong only to you so that external validities on

your possible withdrawal of consent can be evaluated by a third party. The PI will only have passive rights with the records in case of legal defense against you, your legal representative, or your immediate relative(s).

You understand that the prevention on the neurological infection risks, and sudden deaths from the complications of the post-vaccination adverse events are not fully guaranteed. The ethics committee oversees the medical responsibilities of the PI, in case of any negligence of the PI on the responsibilities during your participation. You agree to report any such circumstances to the ethics committee during your participation, and you hold the full rights and autonomy in disagreeing with the ethics committee.

## **PROCEDURES AND PROTOCOL**

For the necessities of intensive care and observations, you agree that the procedures will take place with the convenience of the PI. The first week or two are the most risky periods in the intervention, and you agree that the PI will be closely monitoring your medical situations during the periods, until the PI calls off the alarms. After the critical periods, you can choose to continue the procedures at your own convenience, and report relevant data to the PI / study group. If you choose so, you will truthfully and faithfully take the required medication and report to the PI the frequencies and dosages you actually take during the procedures, and the reasons and circumstances that you have not exactly followed the procedural requirements.

You agree to participate in the necessary tests during the procedure, and agree to have read the study protocols detailed in a separate document.

## **DURATION**

The research takes three months, but does not guarantee the research duration is ample for the cures. The PI agrees to follow your medical circumstances, if you choose to, after the research period, and you agree that if the PI decides another trial is needed, you will consider renewing a new consent to the participation according to the medical necessities. You agree that the PI has the right to adapt your reported medical circumstances for academic purposes without compensation to you and with the premise of deidentification of the data collected that can associate to you personally.

## **RISKS**

Details of the risks are provided in the study protocol in a separate document, and you agree to have read and understood the risks. You confirm that if there is anything that you do not understand in the study protocol, the PI has explained to you and you have comprehended the risks associated to you. You agree that the death risks and disability risks exist prior to the involvement of the study group and PI, and you agree that you or your relatives will not hold the study group and PI accountable if they happen, unless there is concrete proof that such happenings are associated with the negligence of the PI / study group, or are directly caused by the mistreatment conducted by the PI / study group. The PI / study group agree that the study protocol can be used as evidence against them if such occurrences happen.

## **BENEFITS**

The clinical trial may detox the SARS-CoV-2 viral protein pathogens in your system, and hopefully treat the systems on a long-term basis. Your participation will help the research team to determine the validity of the treatment plan designed, and if it works, it will help to advise others who experience the same and similar risks as you. Your participation may help the research team understand further about sebaceous immunobiology, and may lead to new insights on the human pathogens of SARS-CoV-2. However, you agree that the knowledge resulted from the trial may not directly benefit your own medical case, nor the potential commercial and scientific benefits personally to you.

## **REIMBURSEMENTS**

You agree that the research team will not provide any monetary or non-monetary compensation to you for the participation. However, if your participation have led to new discoveries, and you participate in the relevant follow-up studies, the research group will express their gratitudes by reimbursements according to the conditions of available funding for follow-up studies.

## **CONFIDENTIALITY**

You understand that the research group will not actively share the information about your participation in the studies to external sources. All data collected from you by the research group will be deidentified and labelled before publication and sharing. If there is necessities in revealing your identity, the PI or the ethics committee will ask for your permission first before any such decisions. You agree that you will not hold the research team, PI, or ethics committee

liable if you yourself have revealed your participation in the study. Neither do the research team, PI, and ethics committee prohibit you from disclosing your participation in the study, unless it is in a defamatory nature. If any leaks of privacy happen, the ethics committee will take the responsibilities in cooperating with you in seeking appropriate liabilities.

## **SHARING THE RESULTS**

The knowledge that we get from the research will be shared by methods including but not limited to, academic meetings, scientific journal publications, scientific funding, commercial application or investors, etc. The information from the study will be shared with the public so that the validated results can be replicated by anyone with the necessities free of costs and charges from the research team, ethics committee, and PI. No personally identifiable information will be shared from the study results.

## **RIGHT TO REFUSE OR WITHDRAW**

As previously outlined, you have the full autonomy throughout the participation, and disagreeing and refusing any treatment suggested by the PI and research team during the research. In such cases, you agree to discuss with the PI on the reasons for refusal, so that the treatment plan can be adjusted accordingly to best suit your medical necessities.

If you choose to withdraw from participation during any phase of the study, the PI and research team will follow up with you with a 3-day period. The PI and research team will continue their medical responsibilities with you during the period for medical ethics reasons, and

you agree to sign a termination agreement before the 3-day period, exempting the research team and PI from responsibilities on your medical circumstances after the 3-day period.

## **ALTERNATIVE TO PARTICIPATING**

If you do not wish to take part in the research, but consider the study protocol suitable for your medical circumstances, you can freely adopt the materials to your circumstances with your own resources. In such case, the research team, PI, and ethics committee will not be ethically nor legally liable to your adoption of the study protocol. However, you're welcomed to report any suggestions, experiences, and results to the PI with the contact information to improve our research. The team express their gratitudes if you do so.

## **WHO TO CONTACT**

You can reach the PI Yang I. Pachankis by the telephone number +86 189 1056 6992, or email address [yang.pachankis@gmail.com](mailto:yang.pachankis@gmail.com). Email and text messages are highly recommended for that there are a lot of harassment phone calls. The PI will check the email and texts regularly.

Due to the resource limitations of the research, the ethics committee and sponsor is the same person as the PI. Please state the relevance of your contact in the communications.

Address: 2-28-4 Dexinyuan, 1001 Biqing N Rd, Chongqing, 402762, PRC.

## **CERTIFICATE OF CONSENT**



I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant \_\_\_\_\_

Signature of Participant \_\_\_\_\_

Date May 1, 2023

Day/month/year

#### STATEMENT BY THE RESEARCHER/PERSON TAKING CONSENT

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the study protocol will be done.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent Yang I. Pachankis

Signature of Researcher /person taking the consent Yang Pachankis

Date May 1, 2023

Day/month/year