PARTICIPANT/GUARDIAN INFORMATION SHEET

Version 1.1 dated 10 February 2021

Study Title: COVID-19 vaccines Adverse events Response and Evaluation (CARE) Programme: Intensive Monitoring

You/Your ward is being invited by the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, the University of Hong Kong to take part in the research entitled as above. Before you decide you/your ward is to participate, it is important that you understand the purpose and scope of the research. Please take time to read the following information carefully and do not hesitate to seek clarification or additional information.

1. Study Purpose

COVID-19 is a global pandemic with significant impacts on people's lives and health. The COVID-19 vaccine is expected to play an important role in the control of the pandemic. Clinical trials have been conducted in parallel with the development and manufacturing of COVID vaccines to accelerate the approval process. Like other new drugs and vaccines, it is possible that rare adverse events become apparent only after real-world usage, and the adverse reaction profiles may differ between different age groups and among populations with different characteristics. Hence, it is immensely important to closely monitor the safety of the vaccines as massive vaccination programmes are being launched. A comprehensive post-marketing surveillance is needed to monitor the potential adverse events and vaccine failure amid widespread clinical use. Therefore, we are planning to conduct an intensive monitoring to ascertain the details of ALL adverse events inclusive of common adverse events including injection site inflammation, headache and others. The CARE programme is conducted under the remit of Prevention and Control of Disease (Use of Vaccines) Regulation (Cap 599K) for monitoring any adverse event occurred to the recipients associated with the administration of the vaccines.

2. Participation Eligibility

You/Your ward will be eligible to participate in this study if you/your ward is a Hong Kong resident and have received COVID-19 vaccines.

3. Participation and Withdrawal

Your/Your ward's participation is voluntary and is free to withdraw at any time, without giving any reasons. Your/Your ward's rights to medical care and legal rights will not be affected.

4. Procedures

All vaccine recipients will be observed for a minimum of 15 minutes after each injection. Researchers will collect baseline demographics and health status and record any adverse events within the 15 minutes. Each vaccine recipient will be invited to fill in one online survey via SMS/emails at 24, 48, 72 hours and 7, 14, 28 days after each COVID-19 vaccine injection, i.e. a maximum of twelve online surveys, each of which will take around 5 minutes. The last survey for first dose will be omitted if your/your ward's second dose is inoculated on or before the 28th day after your/your ward's first dose. Your or your ward's mobile number and/or email will be collected for communicating information regarding the online surveys. You/ your ward can also choose to fill in paper surveys and hand it over to our researchers afterwards. After finishing the surveys at all time points with regard to the first dose of vaccination, participants will receive a HK$50 supermarket or coffee shop coupon and another HK$100 coupon after completing all the surveys about the second dose of vaccination (i.e. maximum $150 in total for two doses) to compensate for the time commitment.

5. Potential Disadvantages and Risks

There are no particular disadvantages and risks arising from your/your ward's participation in this study.

6. Potential Benefits

The results of this study could inform governments and public health organisations on the appropriate actions regarding the COVID-19 vaccines, including but not limited to enhanced surveillance for specific adverse events, or the revocation of vaccine approval etc. We believe that through participating in this study, you/your ward will benefit indirectly from this study as a member of Hong Kong society.

7. Confidentiality

All data and original documents will be stored in the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, the University of Hong Kong. Original documents will be entered into electronic databases and destroyed 5 years after the conclusion of the study. All personal data will be kept confidential and the data for data analysis would be anonymised. Your/Your ward's data and information may be inspected by regulatory authorities of academic research, such as auditor(s) or the Institutional Review Board/ Independent Ethics Committee.

Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you/your ward enjoy or may enjoy rights for the protection of the confidentiality of your/your ward's personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your/your ward's personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or his office (Tel No. 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

By consenting to participate in this study, you expressly authorise:

- the principal investigator and his research team and the ethics committee responsible for overseeing this study to get access to, to use, and to retain your/your ward's personal data for the purposes and in the manner described in this informed consent process; and
- the relevant government agencies (e.g. the Hong Kong Department of Health) to get access to your/your ward's personal data for the purposes of checking and verifying the integrity of study data and assessing compliance with the study protocol and relevant requirements.

8. Publication of Findings

After the completion of the study, we will publish the research findings in medical journals or share anonymised data with other academic institutions. We may also publicise the findings through the local and international media. Under no circumstances would any personal data be released. The data collected in this study maybe analysed in other related studies that we may conduct in future.

9. Contact Us

This study is conducted by the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, the University of Hong Kong. It has been approved by the Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster. If you have any questions about the rights of research subjects, please contact the Secretary of the Institutional Review Board of the University of Hong Kong/ Hospital Authority West Cluster on 2255 4086. If you have any questions in relation to the study, please email carehk@hku.hk, or contact our research personnel, Ms. Leung at 2831 5110.

10. Source of funding

This study is funded by the Department of Health.