研究名稱：2019 冠狀病毒病（COVID-19）疫苗的免疫原性及持久性：社區縱向觀察性隊列研究（「恆護」研究計劃）
Study title: COVID-19 Vaccine Research (COVAR): A community-based longitudinal observational cohort study on the immunogenicity and duration of vaccine-induced immune responses to different COVID-19 vaccines

參與者須知
Participant Information Sheet

香港大學公共衞生學院誠邀閣下參與本研究。在您決定是否參與之前，請先細閱以下資料以清楚了解本研究的目的、內容、潛在利益和風險。如您在閱讀本須知後有任何疑問或需要更詳盡的資料，請向有關研究人員聯絡。

You are being invited to take part in the above study. Before you decide to join, it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully, and do not hesitate to ask the research personnel if there is anything unclear or if you want more information.

研究背景及目的 Study Background and Purpose

在 2019 年底初發的 2019 冠狀病毒病（COVID-19）及其後的全球大流行，至 2020 年終時已於全球造成數百萬的死亡和重大的經濟影響。COVID-19 由感染 SARS-CoV-2 冠狀病毒（新冠病毒）所引起，感染後病情可以從無症狀，或出現常見呼吸道症狀而促使患者求診但能很快復原的輕症感染，以致出現嚴重症狀需要住院甚至導致死亡。接種 COVID-19 疫苗可預防感染新冠病毒或減低出現嚴重疾病的機會，更可通過增加社區裡群體免疫力來幫助減少社區傳播。香港政府於 2021 年為所有香港居民提供免費的 COVID-19 疫苗接種。不同疫苗配方的安全性及疫苗有效性或存異，例如各疫苗配方對於刺激不同免疫系統反應的能力、疫苗保護效能的持久性、對變種病毒的保護性及降低已接種者傳染性的能力也可能各有不同。此外，其他在社區傳播的呼吸道病毒或疫苗接種計劃如流感疫苗接種可能會影響我們分析 COVID-19 疫苗效能的數據。因此，我們有迫切需要在香港本地進行大規模的社區研究，以全面評估接種 COVID-19 疫苗後的短期接種反應、長期健康狀況和疫苗引起的免疫能力，以及監察於 COVID-19 疫苗接種者中 SARS-CoV-2、流感病毒和其他呼吸道病毒的感染或疫苗接種情況。

我們的研究團隊是來自香港大學的傳染病流行病學專家。我們設計了一項長期研究計劃以彌補有關 COVID-19 疫苗接種的知識缺口，包括接種 COVID-19 疫苗或感染 SARS-CoV-2 後免疫水平隨時間之變化。我們的研究結果將幫助科學家研發更好的 COVID-19 疫苗，判定所需社區疫苗接種率，以及評估重複接種疫苗的需要。再者，研究結果更可幫助衞生當局在未來數年實施更好的疾病防控政策抵抗新冠肺炎大流行。有關其他呼吸道病毒感染和疫苗接種如流感病毒的數據也將能幫助科學家更好地了解呼吸道病毒感染的流行病學和群體免疫。

The recent emergence of the new coronavirus disease 2019 (COVID-19) in late 2019 and the subsequent global pandemic has since caused millions of deaths and significant economic impacts globally by the end of 2020. Infection by SARS-CoV-2, the virus that causes COVID-19, vary widely in disease severity from asymptomatic infection, mild self-limiting infections with common respiratory symptoms that may prompt individuals seeking medical consultation, through to severe disease requiring hospitalization and death. COVID-19 vaccination would provide protection against infection or severe disease, and would also help to reduce community transmission by the accrual of population immunity. The Hong Kong government will offer free COVID-19 vaccination for all Hong Kong residents in 2021. Different vaccine formulations may differ in their safety profiles and vaccine efficacies, as well as capacities in stimulating different

branches of immune responses, duration of protection, protection against mutated strains, and in reducing the contagiousness of vaccinated individuals. Moreover, other respiratory viruses circulating in the community or vaccination programmes such as influenza vaccination may affect how we interpret the data on COVID-19 vaccine effectiveness. Therefore, there is an urgent need to conduct a large-scale community-based study to provide a comprehensive evaluation of short-term adverse events, long-term health outcomes and vaccine-induced immunity of COVID-19 vaccines in Hong Kong, as well as to monitor for SARS-CoV-2, influenza virus and other respiratory virus infections or vaccination among COVID-19 vaccine recipients.

Our team at the University of Hong Kong are experts in infectious disease epidemiology, and have designed a long-term study to measure how immunity against COVID-19 changes over time after COVID-19 vaccination or infection by SARS-CoV-2 (the coronavirus causing COVID-19), because this is one of the major gaps in scientific knowledge. Our findings will help scientists to design better COVID-19 vaccines, to determine the level of community vaccine coverage needed and the frequency of revaccination if needed, and will help health authorities to implement better strategies to control the COVID-19 pandemic in the coming years. Data on other respiratory virus infections and vaccination such as influenza virus will also help scientists to understand better the epidemiology and population immunity of respiratory virus infections.

參與者資格 Participant Eligibility

若您符合以下納入條件，便符合資格參與本研究：

- 18 歲或以上人士；
- 合資格接種由香港政府 2019 冠狀病毒病疫苗接種計劃所提供的任何 COVID-19 疫苗；
- 願意在（如適用）接種每劑 COVID-19 疫苗前、和至少在其一個月及一年後提供血液樣本；及
- 您或您的照顧者有一部家居電話或手提電話作聯繫用途。

You are eligible to join the study if you meet the following requirements:

- Individual aged 18 years old or above;
- Are eligible to receive any COVID-19 vaccine under the Hong Kong government's COVID-19 Vaccination Program;
- Willing to provide blood samples (if applicable) before receiving each dose of vaccination, as well as at least one month and one year afterwards; and
- You or your caregiver have a home phone or cellular or mobile phone for communications purpose.

研究程序 Study Procedure

本研究將於 2021 － 2024 年期間進行。我們會在參與者接種 COVID-19 疫苗後 3 年內，通過定期監測參與者免疫水平變化、急性呼吸道感染和健康狀況（例如不良反應和醫療需要），以評估疫苗效用。在納入研究時，我們將記錄您接種 COVID-19 疫苗的類型。然後，為了評估疫苗引起的即時反應，我們將在您接種每劑 COVID-19 疫苗不久前及其一個月後為您採集血液樣本。我們亦會在您接種每劑 COVID-19 疫苗後一個月內監測可能發生不良反應的情況。隨後，為研究疫苗保護力的持久性，我們將每 6 個月詢問您的健康狀況及其他相關資料，在接種後約第 6、12、24 及 36 個月向您採集血液樣本，並會定期與您聯絡詢問有關您近期任何健康方面的轉變及疫苗接種情況。如您出現急性呼吸道疾病病徵，我們希望於生病起一個月內定期安排家訪，以收集您的呼吸道樣本（如鼻液、鼻腔及咽喉拭子和唾液樣本）進行新型冠狀病毒、流感或其他呼吸道病毒的分析，及記錄您的疾病情況如嚴重程度及使用醫療服務情況。參與者亦可讓我們於上述定期跟進訪談和生病探訪時，或於額外時間如接種每劑 COVID-19 疫苗後的 1 或 7 天、或在接種後每 6 個月，

採集額外血液、呼吸道或糞便樣本，以評估不同免疫系統中其他免疫相關反應。另外，在每一次採集血液樣本同時，我們或會邀請您提供指尖血或唾液樣本進行新冠抗體快速測試。我們將在每次採集樣本前向您作詳細解釋。

我們會為參與者每次採集不超過 20 毫升血液。參與者亦可選擇於每次樣本採集提供額外不超過 20 毫升的血液樣本。

This study will take place between 2021 – 2024. Participants will be followed up for 3 years after vaccination to evaluate vaccine performance, through monitoring changes in immune responses, acute respiratory illnesses and health status (for example adverse events and medical care) over time. At enrolment, we will record the type of COVID-19 vaccine(s) that you have received. Then, to evaluate the immediate vaccine-induced responses, we will collect blood samples shortly before each dose of COVID-19 vaccination, and one month after. We will also collect information on the possible occurrence of adverse events within one month after each dose of vaccination. Subsequently, to study the duration of vaccine protection, we will ask you about your health and other related-information every 6 months, collect blood samples from you at about 6, 12, 24 and 36 months after vaccination, and we will contact you regularly to enquire about recent illnesses or vaccinations throughout the study period. When you suffer from an acute respiratory illness, we would like to arrange regular home visits within one month since the start of the illness to collect illness information and respiratory samples, such as nasal swabs, throat swabs, nasal secretion collected by adsorption ("nasosorption") and/or saliva samples, so as to evaluate whether the illness is caused by SARS-CoV-2 or a different pathogen and illness severity. Participants could also let us collect additional blood, respiratory samples and/or stool samples during the regular or illness visits as described above, or during additional visits 1 or 7 days after each dose of vaccination, or every 6 months after vaccination, to measure other components of the immunity. Separately, during each time of blood collection, we may also invite you to provide finger-prick blood sample to identify COVID-19 antibodies by a rapid diagnostic test. For each sample collection we will explain to you with more details beforehand.

We will collect no more than 20 ml of blood for each blood draw from participants. Furthermore, participants have the option to provide additional blood samples for each blood draw, with additionally no more than 20 ml of blood for each blood draw.

感謝參與 Acknowledgement of Participation

參與此研究費用全免。為答謝您參與本研究所花耗的時間及對本研究的支持，在每次定期研究跟進提供血液及呼吸道樣本後，我們會給予您面額港幣 100 元超級市場禮券；若您提供額外血液或糞便樣本，我們會額外給予您面額港幣 50 元超級市場禮券。在每次因呼吸道徵狀而家訪並提供呼吸道樣本後，我們會給予您面額港幣 50 元的超級市場禮券；若您提供額外血液樣本，我們會額外給予您面額港幣 50 元超級市場禮券。於研究期間，我們或會不時向您發報有關您個人的檢測報告或本研究隊列的整體研究結果。

No cost will be incurred for joining this study. To appreciate your time spent and support for our study, for each visit for blood draw and respiratory samples collection during the regular follow-up, you will receive supermarket coupon valued at HK$100; and if you agree to provide additional blood or stool samples, you will receive an additional supermarket coupon valued at HK$50. Upon the report of an eligible respiratory illness, for each visit with respiratory samples collection, you will receive supermarket coupon valued at HK$50; and if you agree to provide additional blood samples, you will receive an additional supermarket coupon valued at HK$50. Throughout the study, we may also occasionally send you the results of your laboratory testing or the study findings of the cohort as a whole.

潛在風險或不適 Potential Risks or Discomforts

抽血後您可能會出現短暫的輕微疼痛及細小的瘀青。在罕見的情況下，在抽血後您可能會感到頭暈或暈倒。採集鼻液、鼻腔及咽喉拭子、唾液或糞便樣本時不會使人感到痛楚，但有些人或會感到輕微不適或痕癢。

You may experience a short period of slight pain and minor bruising from the blood draw. In some rare situations, you might feel dizzy or faint following the blood draw. It is not painful to collect nasal secretion, nasal and throat swab, saliva or stool samples, although some people may feel minor discomfort.

潛在利益 Potential Benefits

我們相信本研究的參與者作為整個社會的一分子，將可從研究結果間接受益。本研究結果可供政府及各衞生組織參考，以制訂將來適切香港的新冠肺炎疫苗接種策略。

We believe that you, as a member of the society, will benefit indirectly from the findings of this study in your contribution. The results of this study could help the government and health organizations in designing future strategies for COVID-19 vaccines that are better and more suitable for people in Hong Kong.

生物樣本 Biological Specimens

您所提供的血液、呼吸道（包括鼻液、鼻腔及咽喉拭子、唾液）和糞便樣本將會被儲藏香港大學公共衞生學院內。香港大學研究人員或其於其他本地或海外學術機構的科研合作者將會把您提供的樣本進行有關呼吸道病毒的免疫力包括人類基因部份的測試。所有樣本都會在該研究終結後保存十年以允許我們有足夠時間完成以上測試。

All blood, respiratory (including nasal secretion, nasal and throat swab, saliva) and stool samples will be stored in the School of Public Health, the University of Hong Kong, and tested by the research team at the University of Hong Kong or their collaborators at other local and/or overseas academic institutions for testing of immunity against specific respiratory viruses including genetic component of human immunity. Your sample(s) will be stored for 10 years after the conclusion of the study to allow us time to complete these tests.

個人資料保密 Confidentiality of Personal Information

所有數據和正本文件將會儲放在香港大學公共衞生學院內。研究人員會將所有正本文件的資料輸入電子數據庫，並會在研究結束後銷毀所有正本文件。電子數據將會儲存於香港大學已加密的電子數據庫。所有個人資料是絕對保密的，研究人員會以不記名的方式作數據分析。監管學術研究的機構，例如核數師或者研究倫理委員會，亦有可能檢閱你的數據和資料。

有需要的話，每個研究參與者都有權利獲得其個人的數據以及公開報告的研究結果。根據香港法律（特別是「個人資料（私隱）條例」，第 486 章），您有權對您個人資料進行保密，如在本項研究中 或與本項研究有關的個人資料的收集、保管、保留、管理、控制、使用（分析或比較）、在香港內外轉讓、不披露、消除和/或任何方式處理。如有任何問題，您可以諮詢個人資料私隱專員或致電到其辦公室（電話號碼：2827 2827），以適當監管或監督您個人資料保護，以便您能完全認識和瞭解確保遵守法律保護隱私資料的意義。

同意參與該項研究，您明確作出以下授權:
•為了監督該項研究，授權主要研究者及其研究團隊和倫理委員（香港大學及醫管局港島西醫院聯網研究倫理委員會）根據本項研究和本知情同意書規定的方式獲得、使用並保留您的個人資料，並且

•為了檢查和核實研究資料的完整性、評估研究協定與相關要求的一致性，授權相關的政府機構（如香港衛生署）可獲得您個人資料。

All data and original documents will be stored in the School of Public Health, the University of Hong Kong. Original documents will be entered into electronic databases and destroyed at the conclusion of the study. Electronic datasets will be stored in a secured sever in the University of Hong Kong. All personal data will be kept confidential and the data for data analysis would be anonymised. Your data and information may be inspected by regulatory authorities of academic research, such as auditor(s) or the Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster.

You have the rights of access to personal data and publicly available study results, if and when needed. Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you benefit or may benefit from rights for the protection of the confidentiality of your 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 personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or their 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 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 personal data for the purposes of checking and verifying the integrity of study data and assessing compliance with the study protocol and relevant requirements.

參與及退出 Participation and Withdrawal

您的參與純屬自願，您可隨時退出研究而毋須給予任何理由。

Your participation in our study is completely voluntary. This means that you can choose to participate in this study or, at any time, to leave this study without giving any reason.

研究結果 Research Findings

研究結束後，我們會將研究結果透過國際醫學期刊發表，或會把數據以匿名方式給與其他學術團體，亦可能會舉行記者招待會向本地和國際媒體發表我們的研究成果。在任何情況下將不會透露您的個人身份。此外，研究人員或會將這項研究所收集到的數據用於未來研究的數據分析中。

After completion of the study, we will publish our study results in international medical papers or share the data without any personal data with other academic institutions. We may also publish the results through press conferences locally and internationally. Under no conditions would any personal data be released. Furthermore, all data collected in this study may be analysed in other related studies that we may conduct in the future.

主辦單位，資金來源及倫理評審 Organizations, Source of Funding and Ethics Review

本研究是由香港大學李嘉誠醫學院公共衞生學院梁曉瀾博士及高本恩教授籌辦，及由香港食物及衞生局提供資金支持。本研究已獲得醫管局港島西醫院聯網研究倫理委員會的審批。若您對本研究對象的權益有任何疑問，歡迎致電 2255 4086 醫管局港島西醫院聯網研究倫理委員會秘書查詢。

This study is led by Dr. Nancy Leung and Prof. Benjamin Cowling from the School of Public Health, Li Ka Shing Faculty of Medicine, the University of Hong Kong, and financially supported by the Food and Health Bureau of Hong Kong. It has been approved by the Institutional Review Board of the 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 Hospital Authority West Cluster on 2255 4086.

查詢 Enquiries

若您對本研究有任何疑問，請致電本**「恆護」研究計劃**熱線+852 9848 3299 / +852 9130 4428 或電郵致 covar@hku.hk 查詢。
If you have any questions in relation to the study, please contact our **"COVAR" study** hotline at +852 9848 3299 / +852 9130 4428 or email to covar@hku.hk.