# INFORMED CONSENT FORM ADDENDUM REGARDING EMERGENCY USE AUTHORIZED OR LICENSED COVID-19 VACCINES

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| **TITLE:** | A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older |
| **STUDY NAME:** | ENSEMBLE 2 |
| **PROTOCOL NO.:** | VAC31518COV3009<br>IRB Protocol # 20203224 |
| **SPONSOR:** | Janssen Vaccines & Prevention B.V. (Janssen pharmaceutical company of Johnson & Johnson) |
| **INVESTIGATOR:** | Habibul Ahsan, MD<br>5841 South Maryland Avenue<br>MC2000<br>Chicago, Illinois 60637<br>United States |
| **STUDY RELATED PHONE NUMBER(S):** | 773-612-4356 (24 hours) |

You have already read and signed an Informed Consent Form to participate in the ENSEMBLE 2 study. We said we would let you know of any new information during the course of the study that could make you want to change your mind about continuing. The purpose of this form is to tell you about these updates so you can decide if you want to continue participating in the study you are a part of.

All information in the Main Informed Consent Form and HIPAA Authorization still applies.

**THANK YOU FOR YOUR PARTICIPATION IN THIS COVID-19 VACCINE CLINICAL STUDY.**

You may have heard the results of clinical studies on COVID-19 vaccine candidates. These developments are due in large part to clinical study participants like you and show the importance of vaccine research. You may have questions about what this means for the clinical study you are taking part in, even if a COVID-19 vaccine is not yet authorized for use in your country.

**What does the news around Emergency Use Authorization of other vaccines mean to you as a participant in a Janssen COVID-19 vaccine study?**

At the moment, there are no changes to our Janssen COVID-19 vaccine clinical studies. As soon as an investigational vaccine candidate is authorized and distributed for use in your country, we will work with local governments and regulators to make sure study participants like you are not disadvantaged and have the opportunity to be vaccinated through the local health systems if this is an option available to you. In the meantime, you are encouraged to continue to attend your clinical study appointments, to check on your health and report safety data. We are very grateful for your contribution to Janssen's COVID-19 vaccine clinical studies.

**Does the Janssen COVID-19 vaccine clinical study need to continue?**

Yes. It is important that the clinical studies already underway continue to be pursued to find effective vaccines to help end this COVID-19 pandemic. This will not only increase the likelihood of success for developing safe vaccines that work, it will also help to meet the global need for vaccine doses. Therefore, there is no change to Janssen clinical studies researching our investigational COVID-19 vaccine candidate and it is important these studies continue. If you have additional questions or concerns, please reach out to the research team at your investigative site.

**I'm participating in a Janssen ENSEMBLE 2. I am in a priority group eligible to receive another authorized vaccine. What should I do?**

Depending on your country of residence, when a vaccine is authorized, people in priority groups will have the opportunity to receive it first. These priority groups could include people who are most at risk from COVID-19, such as those who live in long-term care facilities and some front-line health care workers. If you are in a priority group and have been invited to receive an authorized vaccine, please contact the research

team at your investigative site who will discuss your options. This may include unblinding you to find out whether you received Janssen's investigational COVID-19 vaccine candidate or placebo.

The study protocol allows for unblinding of individuals who are in a priority group for receiving an authorized vaccine for medical reasons. Even if you are unblinded, we encourage your continued participation in the ENSEMBLE 2 study.

If you are unblinded, and had received the investigational vaccine (not placebo), the research team will discuss the unknown risks of receiving a different COVID-19 vaccine. If you are unblinded and had received placebo, you will be advised to receive the authorized vaccine. In any case, you will not receive the second vaccination initially planned in the current study. Regardless of the unblinding results, and of your decision to take the other vaccine, we urge you to continue in ENSEMBLE 2 study. Your continued participation in the Janssen study will allow us to continue gathering important information pertaining to the study objectives. We ask that you please continue to attend follow-up appointments and follow the advice of the research team. It will be important that we gather information about the safety and effectiveness of all Janssen's COVID-19 studies.

**I'm in a Janssen ENSEMBLE 2 study, but not in a priority group to receive an authorized vaccine. What should I do?**
We ask that you continue to take part in your ENSEMBLE 2 study, continue to track your health status, and to attend all of your follow-up appointments. It is likely to take some time for healthy people under 50 years of age to be invited to receive an authorized vaccine. We ask all participants to continue their participation in the clinical studies.

**What if I want to leave the ENSEMBLE 2 study as a result of the information about other vaccines being made available in my country?**
Study participants can request withdrawal for any reason at any time. However, it is important to note that leaving the study may not mean that you will receive an authorized vaccine right away if you are not identified as part of a priority group.

**IF YOU AGREE TO PARTICIPATE OR REMAIN IN THE STUDY, PLEASE READ AND THEN SIGN BELOW.**

The addendum to the study consent form has important information to help you decide if you want to participate or continue in this study. You will also be given a copy of the document Participant Information Sheet Regarding Emergency Use Authorized or Licensed COVID-19 Vaccines. If you still have questions, please ask the study doctor or study staff, **before** you sign this form.

**Agreement to continue in the study:**

- I have read this information
- It is written in language that I can read and understand
- The updates to the informed consent have been explained to me
- All my questions about the changes described in this form have been answered to my satisfaction
- Based on this information, I agree to continue to take part in this study

**You will receive a copy of this signed and dated Informed Consent Form Addendum.**

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| Printed Name of Participant, in full | |
| Signature of Participant | Date (dd-MON-yyyy) |
| Printed Name of Person Obtaining Consent | |
| Signature of Person Obtaining Consent | Date (dd-MON-yyyy) |
| Printed Name of Investigator, if different from the person obtaining consent | |
| Signature of Investigator, if different from the person obtaining consent | Date (dd-MON-yyyy) |