Patient Consent Form

CONSENT FORM

Title of Project: COVID-19 VACCINATION OF VULNERABLE POPULATIONS (COVULPOP)

---

1. I acknowledge that the nature, purpose and contemplated effects of the project so far as it affects me, have been fully explained to my satisfaction by the research worker and my consent is given voluntarily.

2. The details of the procedure proposed have also been explained to me, including the anticipated length of time it will take, the frequency with which the procedure will be performed, and an indication of any discomfort, which may be expected. I understand that my involvement means a maximum of 28 weeks follow up, the administration of COVID-19 vaccine and/or influenza and/or diphtheria-tetanus-acellular pertussis vaccine, and the collection of up to 6 blood and 1 stool sample.

3. I understand that there are the following risks or possible discomfort: Possible reaction to vaccination – local reaction or systemic reaction with headache and fevers. Discomfort and possible bruising from taking blood.

4. Although I understand that the purpose of this research project is to improve the quality of medical care, it has also been explained that my involvement may not be of any benefit to me.

5. I have been given the opportunity to have a member of my family or friend present while the project was explained to me.

6. I am informed that no information regarding any medical history will be divulged and the results of any tests involving me will not be published so as to reveal my identity.

7. I understand that my biological specimens will be stored in a biobank for future use in order to answer the study questions. Stored samples will be used for the purpose of this research study as outlined in the information sheet and will not be used for any other purpose. I understand that they will be stored for as long as they remain viable, and there are no plans to destroy them within a certain time frame. I understand that project information may be made available to third parties who may use the biological samples in the future to answer the study questions. If this happens, I understand that my identity will not be revealed and I will not be identifiable from the information provided.

8. I understand that genetic analyses are being performed as part of this study, but the study is not specifically analysing for hereditary defects that might affect the future health of myself and my family members. I also understand that my identity will not be linked with the genetic data and my individual results will not be made available to me.

9. I understand that my involvement in the project will not affect my relationship with my medical advisers in their management of my health. I also understand that I am free to withdraw from the project at any stage and withdraw any of my data/specimens that have been collected. Should I do this, any remaining specimens and identifiable data will be destroyed at my request. My withdrawal will not affect my legal rights, my medical care or my relationship with the hospital or my doctors.

10. I understand that I will be given a signed copy of this patient information sheet and consent form. I am not giving up my legal rights by signing this consent form.

11. I understand that the trial will be conducted in accordance with the latest versions of the *National Statement on Ethical Conduct in Human Research (2007) – Updated 2018* and applicable privacy laws.

12. I would like my GP to be informed about my participation in this trial.

    Name of GP:

    Name of participant _____

    Signature of participant _____ Date _____

12. I have explained this project and the implications of participation in it to this volunteer and I believe that the consent is informed and that he/she understands the implications of participation.

    Name of investigator _____

    Signature of investigator _____ Date _____