INFORMED CONSENT FOR GENETIC TESTING OF CASES IN A STUDY

This document (informed consent form) will remain in the patient's record

You, Jose M. Velasquez, 53 years old, residing at 123 Padre Faura St., Barangay 123, Ermita, Manila are invited to participate in the study entitled **"Genetic Determinants of Lipid Levels and Coronary Artery Disease Risk in the Filipino Population"** under the direct supervision of Dr. Jason Gonzales of the Chairman of the Department of Medicine, Philippine Hospital. The co-investigators are Dr. Patricia Gomez of the Institute of Human Genetics, UP-NIH; Dr. Kathleen Valdez, and Dr. Maria Ana Garcia. The investigators of the CVS serve as both investigators and physicians of the patients.

The following are details that you need to understand before you sign this consent form.

1. The study is investigational in nature.

2. This study will last for two (2) years.

3. The study aims to to investigate the genetic determinants of lipid levels and their association with the risk of coronary artery disease (CAD) in the Filipino population, a demographic that is underrepresented in existing studies on dyslipidemia and cardiovascular diseases.

4. The specific objective is investigate the genetic determinants of lipid levels and their association with coronary artery disease (CAD) risk in the Filipino population.

5. The study will involve a total of **9 controls and 5 cases**.

6. In this study, 2.5 ml of blood will be collected from you. This will be stored in EDTA tubes and kept in 4ºC until DNA extraction, which will be done within 14 days from blood collection. All blood will be used for DNA extraction. The DNA samples will be used to determine the genetic background of participants in the study. The extracted DNA will be coded, stored and analyzed at the Institute of Human Genetics, National Institutes of Health Philippines, and will be kept at -20ºC to -80ºC for storage. DNA will be coded with safeguards in place such that privacy and confidentiality are strictly enforced and accidental disclosures of sensitive information avoided. There will be no payment for this procedure.

7. Possible risks include bleeding from the blood extraction site, pain, local reaction to the micropore tape/cotton, and infection. It is advised that you call Dr. Maria Ana Garcia if there is worsening pain, spreading redness around the site, bleeding from the blood extraction site that will not stop with gentle pressure, fever or other concerns. You can go to any emergency room/ clinic/doctor (preferably Philippine Hospital) if any of the above occurs. Medical expenses will be shouldered by the project.

8. You are needed as a control in the study for comparison against the cases as part of the scientific method such that conclusions made are valid, more accurate and precise. This will allow identification of genetic determinants of lipid levels and their association with the risk of coronary artery disease (CAD).

9. You understand that the results of these genetic tests, may determine whether you are susceptible to or at an increased risk for developing another illness or condition. The results may unintentionally reveal information with unknown significance given current scientific knowledge and may increase your and/or your family's anxiety level if they are positive or provide a false sense of reassurance if they are negative.

10. You will receive a P500 monetary remuneration: P200.00 for your transportation expenses and P300.00 for meal expenses during your participation in the study. Furthermore, non- compensation benefits including free medical check-up, specified work-up such as creatinine test, cholesterol profile, liver function test, and health information regarding cardiovascular diseases will be given to you.

11. Potential identification of the possible cause of the disease may provide direct benefit to you, but is limited to conditions and treatment related to coronary artery disease. On the other hand, the genetic information obtained may also be too limited to give particular consequences, and may not help in

alleviating your disease. Therefore, you are required to continue the routine diagnostics according to the protocol of the hospital and to the discretion of the attending physician/s. You and your family will be given genetic counseling and lectures on ways to avoid having the disease. Genetic counseling (pre- and post-test) shall be provided when there is a need to disclose the findings of the genetic study.

12. This investigation will add to the current knowledge and understanding of lipid levels and their association with the risk of coronary artery disease (CAD). Results generated may also be important to the attending physician in dispensing medical advice and genetic counseling.

13. All records or personal information will be kept confidential. Findings from the genetic study will not go into your medical record. These will be coded and kept in secure/locked areas such that confidentiality is maintained. Results of the study may be presented at scientific or medical meetings or published in scientific journals. However, there will be no mention of your name.

14. There will be provisions made to ensure respect for the privacy of the participants and confidentiality of records in which the participants are identified such as coding of samples and keeping all records/DNA samples in secure/locked areas. All DNA samples will be kept in secure and locked freezers with the key kept in secure/locked areas by authorized personnel only.

15. You have the right to know the full results of this study and will be given a copy of the published study results.

16. Genetic information will not be released to others, including family members, without written consent from you.

17. Your participation in this study is voluntary and you can withdraw anytime, for any reason. This will not affect your treatment with your study doctor.

18. In case the informed consent is withdrawn, you will be withdrawn from the study, your record will be deleted from the database, and the sample collected will be properly disposed off.

19. Should you have questions regarding the research and its potential risks or in cases of injury, you can call and ask **Dr. Maria Ana Garcia** of the Cardiology Section (+63 2) 523-2010.

Concerns regarding study-related injuries and patients' rights may be coursed through **Dr. Jason Zamora**, Chair of the National Institutes of Health Ethics Review Panel through the following contact details:

Address: 2nd Floor Paz Mendoza Building, College of Medicine, UP Manila
547 Pedro Gil Street, Ermita, 1000 Manila
Number: +63 2 5222684
Mobile: +63 927 3264910
Email: upmreb@upm.edu.ph

By signing below, you are giving your consent subject to the above conditions.

Jose Velasquez
Jose M. Velasquez
Name and signature of patient

10/01/2022
Date

Jasmine
Jasmine Gutierrez
Witness

K Ferraren
Kyla Ferraren
Witness

Informed consent obtained by:

GSanchez
Gabriel Sanchez, RN
Name and Signature

CONSENT FOR STORAGE OF BIOLOGICAL SAMPLE FOR FUTURE USE

This document (informed consent form) will remain in the patient's record

You, Jose M. Velasquez, 53 years old, residing at 123 Padre Faura St., Barangay 123, Ermita, Manila are invited to participate in the study entitled "**Genetic Determinants of Lipid Levels and Coronary Artery Disease Risk in the Filipino Population**" under the direct supervision of Dr. Jason Gonzales of the Chairman of the Department of Medicine, Philippine Hospital. The co-investigators are Dr. Patricia Gomez of the Institute of Human Genetics, UP-NIH; Dr. Kathleen Valdez, and Dr. Maria Ana Garcia. The investigators of the CVS serve as both investigators and physicians of the patients.

The following are details that you need to understand before you sign this consent form.

1. In this study, 2.5 ml of blood will be collected from you. This will be stored in EDTA tubes and kept in 4ºC until DNA extraction, which will be done within 14 days from blood collection. All blood will be used for DNA extraction. The DNA samples will be used to determine the genetic background of participants in the study. The extracted DNA will be coded, stored and analyzed at the Institute of Human Genetics, National Institutes of Health Philippines, and will be kept at -20ºC to -80ºC for storage. DNA will be coded with safeguards in place such that privacy and confidentiality are strictly enforced and accidental disclosures of sensitive information avoided. There will be no payment for this procedure.
2. Your excess DNA samples will be stored in a -20ºC to -80°C freezer and will be kept at most for 25 years at the Institute of Human Genetics. The samples will be de-coded, de-identified and anonymized, except for age and sex, if used for other relevant studies in the future. However, future protocols will be sent for review c/o an institutional review board prior to usage of your DNA samples. Only authors and research assistants involved in the current project are allowed to handle/use your sample. However, if the samples will be handled/used/stored by anyone who is not part of this study in the future, there will be provisions for approval of the new protocol using anonymized samples from the Ethics Review Board and a Material Transfer Agreement will be made.
3. Should you not consent to the use of your DNA samples for future research, the excess samples collected from you will be properly decontaminated and disposed of after this study.

Please check box and put initial on the line of your choice below (choose only one):

☑ You consent to your own DNA samples being saved and used for future research.
☐ You do not consent to your DNA samples being saved and used for future research.

By signing below, you are giving your consent for genetic testing based on the conditions stated in this document.

Jose Velasquez
Jose M. Velasquez
Name and signature of patient

10/01/2022
Date

Jasmine
Jasmine Gutierrez
Witness

K Ferraren
Kyla Ferraren
Witness

Informed consent obtained by:

GSanchez
Gabriel Sanchez, RN
Name and Signature