A Study of the Genetic Variants Associated with Non-Alcoholic Fatty Liver Disease in Ethnic-Chinese Population in Singapore

Patient Information Sheet and Informed Consent Form

1. Principle Investigator

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Study Sponsor: NUHS Clinician Research Grant

2. Purpose of This Study

You are now being invited to take part in a research study on the *genetic variants associated with NAFLD (Non-Alcoholic Fatty Liver Disease) in the Chinese population in Singapore. It is important to us that you first take time to read through and understand the information provided in this sheet. Nevertheless, before you take part in this research study, the study will be explained to you and you will be given the chance to ask questions. After you are properly satisfied that you understand this study, and that you wish to take part in the study, you must sign this informed consent form. You will be given a copy of this consent form to take home with you.
*genetic variants: DNA sequence variations occurring commonly within a population

The reason for conducting the study is because NAFLD has become a common condition world-wide. In most Asian countries, high quality research data regarding NAFLD is not available. It is as common as 12.2% of the population in the Philippines, 17.2% in Southern China, and up to 42% amongst Asians with diabetes and metabolic syndrome. With the rising rates of diabetes mellitus and obesity in Singapore, we can expect an increasing burden of liver-related disease and death from NAFLD in the near future.

There is a combination of different causes for this disease and genetic factors have long been suspected to play a significant role in NAFLD development. Hence, this knowledge from the study of genetic diversity associated with the condition may eventually lead to more accurate personalized risk predictions and early interventions for susceptible patients in the future.

3. Study Procedures

We will recruit **144 subjects** over a period of one and a half year.

We will retrieve data such as measurements of your blood pressure, height, weight, waist and hip from your routine consultation. In addition, 15ml (3 teaspoons) of blood will also be collected from you. This will be done using a needle and syringe through a vein in your forearm, after cleaning the area with alcohol pad. The blood sample will be coded, meaning no information that may identify you directly will be present. It will be sent to Experimental Therapeutic Center to test your risk of developing NAFLD. No

other genetic test will be conducted to learn about your inherent risk of developing other hereditary disease or non-communicable disease. The results will be communicated to you through your managing doctor.

Blood tests for liver function, cholesterol and blood sugar levels will be performed at the same time, but these are considered part of routine clinical care for any patients with NAFLD.

The whole session will last about 10 to 15 minutes.

4. Your Responsibilities in This Study

If you agree to participate in this study, you should follow the advice given to you by the study team. Also, you have to be prepared to undergo a routine clinical examination and give a blood sample to do a genetic test on your risk of developing NAFLD.

5. What Is Not Standard Care or Experimental in This Study

Measurement of your blood pressure, height, weight, waist and hip measurements, together with the blood tests described earlier are performed as part of standard medical care. Only the data collection, withdrawal of blood and genetic test are performed solely for the purpose of this study.

6. Possible risks and discomfort

The study will not involve an additional needle prick, as blood samples will be taken at the time of routine blood tests. However, the possible risks associated with the blood draws for this research include pain, inflammation, bruising, bleeding and infection at the needle puncture site. Light-headedness and fainting may also result from the blood draw procedure. This blood obtained during the course of study will be stored and analysed only for the purposes of this study for a period not exceeding 3 years and will be destroyed after completion of the study.

7. Possible Benefits

Your participation in this study will add to the medical knowledge about NAFLD and its associated genetic variants.

8. Confidentiality

All study information will be kept fully confidential. Clinical data will be coded (de-identified) and categorized in database for further references. Your sample and clinical records will be identified only as your initials with a study number. Study records will be accessed only by personnel directly involved in the research. Information about study subjects will be kept confidential and managed according to Singapore regulatory requirement. Your records, to the extent of the applicable laws and regulations, will not be made available to the public. No names will be mentioned in the report of any research arising from this study.

By participating in this research study, you are confirming that you have read, understood and consent to the Personal Data Protection Notification available at http://www.nuhs.edu.sg/personal-data-protection.html.

Data collected and entered into the Case Report Forms are the property of NUHS. In the event of any publication regarding this study, your identity will remain confidential.

9. Cost and Payment

This study will not involve any special visits or treatments. Consequently, no reimbursements will be issued for costs of participation. Blood collection, genetic tests, physical examination and questionnaire administration performed for this research is at no charge to you. Charges related to the usual management of your condition and the standard medical care is to be borne by yourself.

10. Compensation

If you follow the directions of the doctors in charge of this study and you are physically injured due to the procedure given under the plan of this study, we will pay the medical expenses for the treatment of that injury through the NHG Clinical Trial Compensation Insurance Scheme.

By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

11. Contacts for questions or problems

For answers to any questions about the study please contact:

Principal Investigator, Dr Lee Guan Huei (Tel: 6779 5555)

Study Research Nurse (Tel: 6772-4039)

The study has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval. If you want an independent opinion of your rights as a research subject you may contact the NHG Domain Specific Review Board Secretariat at 6471-3266.

If you have any complaints about this research study, you may contact the Principal Investigator or the NHG Domain Specific Review Board Secretariat.

12. Alternatives to Participation

If you choose not to take part in this study, you will receive standard care for your condition. In our institution this would be continuing monitoring or treatment if required.

13. Voluntary Participation

Your participation in this study is voluntary. You may also discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision not to take part in this study or to stop your participation will not affect your medical care or any benefits to which you are entitled. If the investigator considers you to have a disease or condition that makes you unsuitable to continue in the study, you may be withdrawn from the study without your consent. In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you will be informed in a timely manner by the Principal Investigator or his/her representative.

The blood sample collected for the study will be deemed to be gifted to National University Hospital and will not be returned to you. However, you retain your right to ask the Principal Investigator to discard or destroy any remaining samples if they have not been anonymised.

Any data that have been collected until the point of withdrawal will be kept and analysed to enable a complete and comprehensive evaluation of the study.

INFORMED CONSENT FORM

Protocol Title:
A Study of the Genetic Variants Associated with Non-Alcoholic Fatty Liver Disease in Ethnic-Chinese Population in Singapore**.**

Principal Investigator & Contact Details:
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Tel: (65) 6779 5555

I voluntarily consent to take part in this research study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to my satisfaction.

By participating in this research study, I confirm that I have read, understood and consent to the (Institution) Personal Data Protection Notification. I also consent to the use of my Personal Data for the purposes of engaging in related research arising the future.

I agree to allow the study team to store my biological samples and data for any future research.

I agree to allow the study team to store my biological samples and data for future related research limited to non-alcoholic fatty liver disease.

I disagree to allow the study team to store my biological samples and data for any future research.

_____	_____	_____
Name of Participant	Signature	Date

Translator Information
The study has been explained to the participant in _____*<language>* by

_____*<insert name of translator* >.

Investigator Statement
I, the undersigned, certify that I explained the study to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of her participation in the study.

_____	_____	_____
Name of Investigator / Person administering consent	Signature	Date

Witness Statement

I, the undersigned, certify to the best of my knowledge that the participant signing this informed consent form had the study fully explained in a language understood by him / her and clearly understands the nature, risks and benefits of his / her participation in the study.

_____	_____	_____
Name of Witness	Signature	Date