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GENETIC AND ENVIRONMENTAL RISK FACTORS FOR DIABETIC NEPHROPATHY AMONG SINGAPOREANS WITH TYPE 2 DIABETES MELLITUS

PATIENT INFORMATION SHEET
Version No: 10 Date: (28/07/2011)

Principal Investigator:
Dr Daniel Ng, National University of Singapore (NUS)

NHG Site Principal Investigators:
Dr Helen Leong, National Healthcare Group (NHG) Polyclinics
Dr Winston Kon, Tan Tock Seng Hospital (TTSH)
Dr Stanley Liew, National University Hospital (NUH)

I. Research Details:
Protocol Title: Genetic and environmental risk factors for diabetic nephropathy among Singaporeans with type 2 diabetes mellitus

II. Purpose of the Research Study
You are being invited to participate in a research study.

Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. You must read and sign this informed consent form. You will be given a copy of this patient information sheet to take home with you. You are being invited because you have been diagnosed with type 2 diabetes.

This study is being performed in order to find out what environmental and genetic factors cause diabetic nephropathy among Singaporeans with type 2 diabetes.

This study will recruit 5480 subjects from NHGP polyclinics including Clementi Polyclinic and hospitals including NUH and TTSH over a period of two years. About five thousand subjects will be involved in this study.

III. What Procedures will be followed in this Study
If you take part in this study we will need to get relevant information from your medical records kept by various clinics, hospitals and national disease registries in Singapore. You will also be required to donate a small volume of blood (about 10 ml). A sample of urine (~50 ml) may also be collected from you. These samples will be obtained annually by trained staff during your normal follow-up in the clinic over the next 20 years. A trained interviewer will also ask you about your family members, questions on your lifestyle (such as smoking habits) and medical history that will help us in our study.

Your participation in the study will last for 20 years. You will be followed up during your subsequent regular visits.

IV. Storage and Use of Samples for Future Studies
Samples of blood and urine obtained during the course of this study will be stored for the purpose of future research. These specimens will be transferred to National University Health System (NUHS) Tissue Repository where DNA (the genetic material that distinguishes different people from each other) will be extracted from your blood. The DNA, your blood and/or your urine samples and their constituent components will be used for scientific analysis.

You can decide not to let us store your specimen and still be in this study. Your specimen will be discarded after this initial study.

V. 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. You should be prepared to continue your regular visits to the clinic/hospital and undergo all the procedures that are outlined above.

VI. Possible Risks and Side Effects
Obtaining blood may cause pain, bleeding, bruising, or swelling at the site of the needle stick. Fainting or infection rarely occurs.

VII. Possible Benefits from Participating in the Study

There is no assurance you will benefit from participation in this study. However, your participation in this study may add to the medical knowledge about the genes and environmental risk factors which may be responsible for diabetic kidney disease.

VIII. Costs & Payments if Participating in the Study

You will not be charged for the blood draws and urine samples collected from you. You will not be paid for participating in the study.

IX. Voluntary Participation

Your participation in this study is voluntary. You may stop participating in this study at any time. 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 you decide to stop taking part in this study and wish to have your samples destroyed, you should inform the Principal Investigator who will arrange for the removal all your information pertaining to the study and destroy any unused DNA and samples that you have already donated. Your doctor, the Investigator and/or the Sponsor of this study may stop your participation in the study at any time if they decide that it is in your best interests. They may also do this if you do not follow instructions required to complete the study adequately. If you have other medical problems or side effects, the doctor and/or nurse will decide if you may continue in the research study.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you or your legal representative will be informed in a timely manner by the Principal Investigator or his representative.

X. Compensation for Injury

If you follow the directions of the doctors in charge of this study and you are physically injured due to the trial substance or procedure properly given under the plan for this study, NUS will pay the medical expenses for the treatment of that injury. 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.

XI. Who to Contact if You Have Questions

If you have questions about this research study and your rights, you may contact the call centre at 6773 8957.

In case of any injuries during the course of this study, you may contact the following Site Principal Investigator(s): Dr Helen Leong (NHG Polyclinics, Tel: 63552790), Dr Stanley Liew (NUH, Tel: 67722597) or Dr Winston Kon (TTSH, Tel: 63577881) depending on the location where you were recruited into the study.

If you want an independent opinion of your rights as a research subject you may contact the NHG Domain-Specific Research Board Secretariat (Attn: Sujatha Sridhar) at 6471-3266 and/or Mr Chan Tuck Wai (NUS-Institutional Review Board) at 65161234.

If you have any questions about the NUHS Tissue Repository, please contact Dr Eng Chong Boon (6772 2379).

XII. Confidentiality of Study and Medical Records

Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available.

However, NUS, Regulatory Agencies and NHG Domain-Specific Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of your information public.

By signing the Informed Consent Form attached, you or your legal representative is authorizing such access to your study and medical records. Retinal photographs that are taken as part of standard care will also be accessed for research. Data collected and entered into the Case Report Forms are the property of the National University of Singapore. NUHS Tissue Repository will have no possession of any of your personal information at any time. In the event of any publication regarding this study, your identity will remain confidential.

PATIENT CONSENT SHEET
Version: *Number 10* Date: 28/07/2011

Protocol Title:
Genetic and environmental risk factors for diabetic nephropathy among Singaporeans with type 2 diabetes mellitus

Principal Investigator:
Dr Daniel Ng, National University of Singapore

NHG Site Principal Investigators:
Dr Helen Leong, National Healthcare Group Polyclinics
Dr Winston Kon, Tan Tock Seng Hospital
Dr Stanley Liew, National University Hospital

Consent to participate in this research study:
I voluntarily consent to take part in this research study.

I have fully discussed and understood the purpose and procedures of this study.

I agree to allow samples of my blood and urine to be used for this present study of environmental and genetic factors in causing diabetic nephropathy.

I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to the best ability of the investigator recruiting me.

This study has been explained to me in _____(language)

on _____ (date) by _____(name of translator).

Consent for medical information to be collected from records / registries
I agree/do not agree to allow my relevant medical information to be gathered from medical records and Singapore's national disease registries. This information will be used in this study on diabetic kidney disease.

Consent for storage and use of my samples for future research
I agree/do not agree to allow samples of my blood and urine to be stored and used for future research on risk factors for diabetes and its other complications.

Consent for use of my medical information for future research
I agree/do not agree for medical information obtained for this study to be used for future related research on risk factors for diabetes and its other complications

Name of Patient	Signature	Date
Name of Witness	Signature	Date

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

Name of Consent-taker	Signature	Date