

PATIENT INFORMATION SHEET

Study title: Singapore Consortium of Cohort Studies (SCCS)- Diabetic Cohort (DC)
Principal Investigator: Prof Chia Kee Seng, National University of Singapore (NUS)
SCCS Hotline: 67738957

What is this research study about?

This study is being performed in order to find out what environmental and genetic factors cause diabetes and its complications among Singaporeans. You are being invited because you have been diagnosed with type 2 diabetes. This study will recruit 7000 subjects from various polyclinics and hospitals over a period of five years.

What is involved in the study?

There will be no medicines to take and no experimental treatments to undergo in this study.

- *Interview*

A research staff will approach you during your clinic visit for an interview. He or she will ask you, questions on your lifestyle (such as diet, smoking/tobacco consumption, exercise), your medical history and relevant family medical history. The questionnaire should take approximately 45 minutes to complete. It is alright to skip any question you don't want to answer, except NRIC; which is essential for recruitment and re-contact.

- *Blood and/or urine donation*

You will also be required to donate a small volume of blood (about 15 ml). A sample of urine (~20 ml) may also be collected from you. These samples will be obtained during your normal follow-up in the clinic.

- *Re-contact*

You may be contacted later to obtain additional health information or to clarify any uncertainties regarding the information collected. It is also possible that researchers may contact you in 3-5 years time to reassess your health status. Even if you participate in this study, you can refuse to participate in later studies.

- *Record linkage*

We will also ask for your consent to allow us to check on your health status by contacting your doctor, the National Disease Registry Office or your medical records, either for this current research or future research. This information is very useful for us to study the effects of lifestyle on diseases.

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.

Why should I donate blood and urine for storage and future research?

Samples of blood and urine obtained during the course of this study will be stored for the purpose of future research. Researchers at the National University of Singapore and other healthcare/ research institutions are trying to learn more about diseases. Your blood and urine can be used to study different diseases. Blood contains markers that may be indicative of the condition of the body, and can also be a source of DNA (the genetic material that distinguishes different people from each other) for the study of genes. Your samples will be used together with samples from many other donors in research studies. Some of the research findings may help doctors and scientists develop new products, such as drugs and diagnostic tests leading to better prevention and treatment of diseases. However your samples will only be used for studies that have been approved by a relevant Institutional Review Board (IRB). The objective of an IRB or research ethics committee is to protect the rights and welfare of human research subjects in research activities.

If you agree to provide a blood sample for this study, we will draw about 15 mls (1.5 tablespoons) of blood from a vein in your arm. This will be stored at the Singapore Tissue Network (STN). STN is a national tissue repository (like a Bank) and is a central storage for research tissue and blood in Singapore. It is a non-profit organization funded by a government agency, namely the Agency for Science, Technology and Research (A*STAR) established to support biomedical research initiatives in Singapore. Your urine sample will also be stored at STN.

Do commercial companies have access to my blood and urine?

The main aim of our research is to improve public health. However, your blood and/or urine may be used for the development of diagnostic procedures or new treatments for major diseases by commercial firms. These projects must be approved by an Institutional Review Board. The approval process takes into consideration the expected future benefits of the proposed tissue usage, whether these be scientific, medical, or economic benefits, to Singapore as a whole. The process and criteria for approving requests from commercial companies will be at least as careful as for not-for-profit research. While these researchers may pay the costs for the distribution of your specimen such as preparation, packaging and shipping, but your tissue samples will not be sold to anyone for our financial gain or commercial profit.

Will I benefit from the research trial and/or research done on my samples?

Your donation of blood and/or urine is regarded as wholly voluntary and is treated as an outright gift. There will be no medical or personal benefit to you arising from the donation of your blood and/or urine or from the research conducted using such samples. You will not have access to the results of the research conducted on your own blood and/or urine. However, the results of research may be beneficial to future patients.

What are the risks of taking part in the study?

The risks of drawing blood include brief pain, slight bruising, and rarely, infection where the needle went in. We take every precaution to prevent infection. Some people feel dizzy when they have blood drawn, but this goes away when the person lies down. Basic first aid treatment will be available if required during the physical examination and venepuncture.

We do not expect any injury to result from participation in this study and as such, no compensation from injuries is anticipated. As the study results will not be entered into your medical records, your health insurance will not be affected in any way.

Is there any cost or payment involved in the research trial?

It does not cost you anything to take part in this study and you will not be charged for any tests. You will not be paid for participation in this study. In the unlikely event that you are injured while giving a blood sample, we will give you first aid and direct you to proper health treatment. This paragraph does not waive any of your legal rights.

Will I find out results of the research?

Neither you nor your doctor will receive the results of other research done with your donated samples. Only anonymized samples will be used for analysis and research purposes. This can take a long time and samples may be required from many people before any conclusive results are known. Results from research using your samples may not be ready for many years and will probably not affect your care right now.

Will researchers have access to my medical records?

Certain information that forms part of your medical record may be required for interpreting research results. Some examples include your age, gender, past health history, details of your present illness and family history of illnesses. Such information will be stored in SCCS and STN's databases, and only certain approved researchers will be allowed access to the information.

How will my privacy be protected?

To ensure your samples and medical information cannot be linked to you, the samples and medical information collected will not contain your identifiable personal data. Instead, these will be replaced by code numbers. It will only be possible to retrace the link between the personal data and the codes by a decoding step. This decoding only takes place under special circumstances and approval needs to be given by an official ethics committee or institutional review board that oversees the ethical aspects of the research.

When results of this study are reported in medical journals or at scientific meetings or used for research, the people who take part are not named and identified. However, medical records may be inspected at some future date by regulatory authorities to verify the information collected and that strict confidentiality of this information will be preserved.

What happens next?

Once you have read this pamphlet, the researcher will make sure that all your questions are answered. Your signature on a Consent Form is required to indicate whether or not you agree to take part in the study. The choice of whether or not to take part is up to you. You do not have to explain your decision to anyone; you just have to say 'yes' or 'no'.

Can I change my mind if I do not want to participate and/or donate my blood and urine after I have signed or donated?

You can withdraw from the research at any time without giving reasons. You can notify us and we will terminate (a) your participation in the study and/or (b) remove all data derived from your participation and/or (c) destroy any unused blood and/or urine that you have already donated.

Who is conducting this study and whom do I call if I have questions or problems?

This study is conducted by the Centre for Molecular Epidemiology at the National University of Singapore. **The principal investigator (person in charge of this research) is Prof Chia Kee Seng. You may call our hot line at 67738957.** If you have any questions concerning research ethics for this study, or your rights in this study, you can contact a member of the NUS-Institutional Review Board (Attn: Mr Chan Tuck Wai) at Tel:65161234.

If you have any questions about the Singapore Tissue Network, please call 6478 8489.