

PARTICIPANT INFORMATION SHEET

Study title: Singapore Consortium of Cohort Studies (SCCS)- Multi-ethnic cohort (MEC)

**Principal investigator: Prof Chia Kee Seng, National University of Singapore
SCCS-MEC hot line: 64789608**

You are invited to participate in a research. This information sheet provides you with information about the research. The Principal Investigator (the research doctor or person in charge of this research) or his/her representative will also describe this research to you and answer all of your questions. Read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

What is this research study about?

The purpose of our research is to learn more about how factors like diet, exercise and smoking are important for heart disease, diabetes, stroke and other common diseases in Singapore. This will help decide if changing these factors can prevent disease or keep it from getting worse. Other aims include evaluating your vision and whether you have any eye problems.

Who can take part in this research?

Participation is through invitation only. People who can take part in this research include:

- 1) Singaporeans and permanent residents of Singapore;
- 2) between age 21-75; and
- 3) of Chinese, Malay and Indian ethnic groups.

Due to the nature of this study, persons with the following medical conditions or history are not suitable to participate:

- 1) Cancer;
- 2) Stroke;
- 3) Heart diseases;
- 4) Renal failure (i.e. undergoing dialysis, on a catheter or has very high creatinine levels);
- 5) Mental illness; and
- 6) Pregnancy.

What is involved in the research?

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

▪ *Interview*

Initially, trained interviewers will contact you and visit you in your home or at a place which is convenient to you. During this time, they will ask you to fill out a survey about your health, diet, and exercise, and your use of tobacco, alcohol, and medicines. It is alright to skip any question you do not want to answer, except NRIC; which is essential for recruitment and re-contact. The questionnaire will take approximately 1 hour to complete. The information will be entered into a database. Certain clinical information such as year of birth, gender, ethnicity, ethnicity of parents, status, diagnosis, family history etc will be transferred to the Singapore Tissue Network (STN); no personal information will be kept at STN. You will then be asked to attend a basic health screening on a separate day.

▪ *Basic Health screening*

The health screening will take approximately 1½ hr. Our research staff will confirm an appointment with you. You will be asked to fast (no food or drinks, except plain water) from 10 pm the night before (or for 10-12hr prior to the health screening). If you have a medical condition (e.g. diabetes) or/and on any medication, please consult the doctor before fasting. During the health screening, nurses and research assistants will:

- 1) measure your weight, height, waist and hip circumferences, and blood pressure;
- 2) measure the blood pressure at your ankle and arm; and

- 3) use an instrument to determine the functional status of the nerves supplying your feet.
- 4) obtain samples of blood and urine for future studies and genetic research;
- 5) obtain blood sample for sugar, cholesterol and creatinine tests, and urine for protein level measurement;
- 6) take photographs of the back of your eye (the retina). We will ask for your permission to instill eye drops to dilate the pupils;

▪ *Re-contact*

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

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

Researchers at the National University of Singapore (NUS) and other healthcare/ research institutions are trying to learn more about diseases. Your blood and urine can be used to study different diseases. For example, blood contains markers that may be indicative of certain conditions of the body, and it 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.

If you agree, we will draw about 40 mls (about 4 tablespoons) of blood from a vein in your arm and/or collect about 20mls of urine. Your samples will be stored at 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. STN may also “grow” more of your blood cells in the laboratory to produce DNA, which will be used only for research.

In addition, your samples will be stored for future research. Any researcher, including those that are part of the present research, who would like to have access to your samples will need to obtain approval from an Institutional Review Board (IRB) to ensure that the study is ethically and scientifically sound. The objective of an IRB or research ethics committee is to protect the rights and welfare of human research subjects in research activities.

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 IRB. The approval process takes into consideration the expected future benefits (scientific, medical, or economic) of the proposed tissue usage, to Singapore as a whole. The process and criteria for approving requests from commercial companies will be as careful as for not-for-profit research. While these researchers may pay the costs for the distribution of your tissue samples such as preparation, packaging and shipping, your 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. As a voluntary donor, neither

you nor your estate will receive any benefits, commercial or otherwise, from your participation in this research nor from the use of your blood/urine or any substance, material, results or data derived from it, or modified versions of it. However, the results of research may be beneficial to future patients.

Your donated blood and urine may lead to research discoveries that may yield financial gain or profit to the companies or institutions that develop the new treatments or diagnostic procedures. We may get a patent on these. We may also license these, which could give a company the sole right to make and sell products or offer testing based on the discovery. Some of the profits from this may be paid back to the researchers and the organizations doing this research.

What are the risks of taking part in the research?

The dilating eye drops may cause some discomfort. You will experience blurred vision for 1-3 hours. As a consequence of this blurred vision, you may be more prone to slipping, falling down, possible clumsiness etc. You are encouraged to be accompanied by another adult. There is a very small risk of acute glaucoma (raised pressure in the eye; you may experience some pain) after dilation of pupils (about 1 in 5000 people). You will be monitored for signs of acute glaucoma after dilation. There is also a risk of mild local allergic reaction to the eye drops. On the rare occurrence of these complications, you will be referred to a doctor of your choice for appropriate treatment. You will have to bear the charges of the treatment yourself.

The risks of drawing blood include slight pain, 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. 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 at your own cost.

As the research results will not be entered into your medical records, your health insurance will not be affected in any way.

Are there any cost or payments involved in the research trial?

It does not cost you anything to take part in this research and you will not be charged for any tests. You will not be paid for participation in this research. If you attend and complete your health screening, you will be reimbursed \$50 per person for your time and effort. This paragraph does not waive any of your legal rights.

Will I find out results of the research?

Following the health screening, you will be provided with a copy of the results of your blood sugar, blood cholesterol, blood pressure, urine protein level and body mass index. You should feel free to discuss these results with your own doctor. The research team will not provide you with a medical assessment or treatment beyond giving you the results.

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 can take a long time and requires samples from many people before results are known. Results from research using your samples may not be ready for the immediate future.

Will researchers have access to my medical records?

Certain information that forms part of your medical record may be required for interpreting research results. With your permission, only SCCS staff will have access to these medical records to obtain the relevant data. Examples of such data 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 databases, and only certain approved researchers will be permitted 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 for research and storage. 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 IRB that oversees the ethical aspects of the research.

When results of this research 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 to ensure strict confidentiality of this information is preserved.

What happens next?

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

There are 2 consent forms for the research. Consent Form A documents your consent to provide health data for research. Consent Form B documents your consent with regards to your biological samples and health screening results.

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 (a) terminate your further participation in the research and/or (b) destroy any unused blood and/or urine that you have already donated. Such a withdrawal will prevent information about you from contributing to further research and analyses, but it will not be possible to remove your data from analyses that have already been done.

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

This research is conducted by the Centre for Molecular Epidemiology at NUS. **The principal investigator (person in charge of this research) is Professor Chia Kee Seng.**

If you have any questions about:

- 1) this research — call the MEC hotline at 64789608; or
- 2) STN — contact Ms Lim Lee Yan at 6478 8489; or
- 3) the research ethics for this study, or your rights in this research — contact a member of the NUS IRB (Attn: Mr Chan Tuck Wai) at 65161234.