

PARTICIPANT INFORMATION SHEET

Study title: Re-visiting the Singapore Consortium of Cohort Studies (SCCS)- Multi-ethnic cohort (MEC): a Pilot

Principal investigator: Prof Chia Kee Seng, National University of Singapore

SCCS 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 researchers understand if changing these factors can prevent disease or keep it from getting worse.

The specific aims of this study are:

- (i) To capture any changes in these factors since the previous survey and health screening;
- (ii) To obtain information about the current state of health of the cohort participants;
- (iii) To study the relationship between body fat and bone health; and/or
- (iv) To study variation in blood lipid and metabolite levels among different individuals and different ethnicities.

Who can take part in this research?

You were selected as a possible participant in this study because you have already participated in a survey by the:

- (i) Multiethnic Cohort (MEC);
- (ii) Singapore Cardiovascular Cohort Study (SCCS2); or
- (iii) Singapore Prospective Study Program (SP2).

We expect to recruit 1000 participants in this study.

What is involved in the research?

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

A) 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 some surveys about your health, well-being, lifestyle, diet, 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 interviews will be administered at 2 separate time points within 2 weeks and each session will take approximately 1hr. The information will be entered into a database. You will then be asked to attend a health screening on a separate day.

B) Health Screening

The health screening may require up to 3 visits. Our research staff will confirm the appointments for each visit with you.

Visit 1

You will be asked to fast (no food or drinks, except plain water) for 10-12hr prior to this visit. If you have a medical condition (e.g. diabetes) or/and on any medication, please consult the doctor before fasting. During the first visit which will take about 1½ hr, nurses and research assistants will:

- 1) measure your weight, height, waist and hip circumferences, and the skinfold thickness of your arms, legs and trunk;
- 2) measure the blood pressure at your ankle, arm and near your heart using non-invasive measuring devices;
- 3) use an instrument to determine the functional status of the nerves supplying your feet.
- 4) obtain samples of blood (up to 31 ml) and urine (up to 6 ml) for future studies and genetic research*;
- 5) obtain blood sample (approximately 9 ml) for sugar, cholesterol and creatinine tests, and urine (approximately 14 ml) for protein level measurement*; and/or
- 6) use an instrument to study the rhythm of your heart. You will be asked to undress to the waist and sticky pads called electrodes will be stuck to your chest, arms and legs.

Visit 2

You may not be suitable for this visit if you have certain medical conditions. These include:

- 1) cardiovascular disease;
- 2) cancer;
- 3) condition requiring high dose steroid medication;
- 4) presence of metallic body replacement parts or inserts; or
- 5) (for women) being potentially pregnant.

This visit will take up to 1¾ hour. Depending on your medical condition, some or all of the following procedures will be performed:

- 1) a bone densitometry scan to measure the bone density of your spine and hip;
- 2) a scan of your whole body muscle and fat; and /or
- 3) a computed tomography (CT) scan of your chest to measure the amount of fatty deposits in the arteries supplying blood to your heart.
- 4) a quantitative computed tomography (QCT) of your hip and spine to measure the volumetric bone density of your spine and hip and dimensions of the hip.

The venue for Visit 1 and 2 is at the AsiaMedic Specialist Centre, 350 Orchard Road #08-00 Shaw House, Singapore 238868.

Visit 3 (applicable to selected participants only)

360 selected participants (out of 1000 participants) will be asked to allow a 13 ml blood sample to be used for a study on human variation in blood lipid and metabolite levels. This blood sample will be immediately processed for analysis and not be stored. The blood will be taken at the Department of Epidemiology and Public Health, Yong Loo Lin School of Medicine, National University of Singapore, MD3, 16 Medical Drive, Singapore 117597.

In total, the total volume of blood to be drawn from a vein in your arm will be **40 ml** (about 4 tablespoons) and a total volume of **20mls of urine** will be collected in this research study.

C) 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.

D) 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 Registry of Diseases 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.

* Selected participants will provide this at Visit 3

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.

Your samples (up to 31mls of blood and 6mls of urine) will be stored at the National University Health System (NUHS).

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 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.

CT and bone densitometry scanning are routine tests done all over the world and the radiation doses used in our study are low. The total dose of radiation is less than what an average person would receive over 3 years from background radiation. There is always a small additional chance of cancer from the radiation but it is very small, at less than 0.0005.

No research results will be entered into your medical records. Therefore, your health insurance will not be affected in any way by your participation in this study.

Important information for women participants

The effect of radiation from the DXA and CT scans on a baby's development is not known. Therefore, pregnant and breast-feeding women may not take part in this study. Women who have a chance of becoming pregnant before study entry should not take part.

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 be reimbursed for your time and effort in the following ways:

Procedures completed	Reimbursement amount per person
Interviews	\$30
Health screening visit 1	\$50
Health screening visit 2	\$30
Health screening visit 3	\$50

This paragraph does not waive any of your legal rights.

Will I find out results of the research?

Within 4 weeks of the health screening, you will be provided with a copy of the results of your health screening.

The results may include:

- 1) blood creatinine, sugar and cholesterol;
- 2) blood pressure;
- 3) urine protein level;
- 4) body mass index;
- 5) spinal and hip bone density; and/or
- 6) a measure of the amount of calcified deposits in the arteries supplying blood to the heart.

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.

It is important to realize that while CT scans are routinely performed for diagnostic purposes for various medical reasons in clinical practice, this scan is done purely for research purposes. As such, it is not optimized for detecting abnormalities outside our research and may not pick up abnormalities even if they are there. Nevertheless, if there are exceptional findings of medical relevance, we will let you know.

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 and / or research data?

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 databases, and only certain approved researchers will be permitted access to the information.

Coded research data collected from this research study may be shared with other researchers, with your permission.

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 3 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. Consent Form C documents your consent to undergo the scans and provide a blood sample for the study on human variation in blood lipid and metabolite levels.

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 SCCS hotline at 6478 9608; or
- 2) 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 6516 1234.

CONSENT FORM A**Study title: Re-visiting the Singapore Consortium of Cohort Studies (SCCS) - Multi-ethnic cohort (MEC): a Pilot**

Principal investigator: Prof Chia Kee Seng, National University of Singapore
SCCS hot line: 6478 9608

I agree to provide my NRIC number for the use of this research. Yes No

I agree to participate in the survey about my overall health, diet, exercise and quality of life; my use of tobacco, alcohol and medicines; and use of healthcare services. Yes No

I agree to allow researchers to confirm my health status by contacting my doctor. Yes No

I agree to allow researchers to confirm my health status by contacting the National Registry of Diseases Office. Yes No

I agree to allow my relevant medical information to be gathered from my medical records for this study. Yes No

I agree to allow my relevant medical information to be gathered from my medical records for future research. Yes No

I agree to allow the sharing of my coded research data in this research study with other researchers. Yes No

I have been given a chance to ask questions and feel that all of my questions have been answered. I know that participation in this study is my choice and that refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled. I may also discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled. I have been given a copy of the participant information sheet that explains the use of my information, blood and/or urine in this research, and consent form to keep. I will not have any rights to any commercial benefits that result from this research. I also agree that I will not derive any monetary or other benefits from this research.

I have been informed that any questions pertaining to this research can be directed to SCCS at 6478 9608. Any questions I have regarding my rights as a research subject can be directed to the National University of Singapore-Institutional Review Board (Attn:Mr Chan Tuck Wai 6516 1234).

CONSENT FORM A**Study title: Re-visiting the Singapore Consortium of Cohort Studies (SCCS) - Multi-ethnic cohort (MEC): a Pilot**

* This research has been explained to me in _____ (state language), which I understand, by _____ (name of translator as per NRIC).

Name (as per NRIC) of participant

NRIC (participant)

Signature/ thumb print (participant)

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Day Month Year

I observed the process of consent. The prospective participant read this form, was given the chance to ask questions, appeared to accept the answers, and signed to enroll in the study.

Name (as per NRIC) of consent taker

Signature/ thumb print (consent taker)

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Day Month Year

Name (as per NRIC) of translator

Relationship to participant

Signature/ thumb print (translator)

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Day Month Year

* Include this section if participant is unable to understand English and read any of the translated consent documents available.

CONSENT FORM B**Study title: Re-visiting the Singapore Consortium of Cohort Studies (SCCS) - Multi-ethnic cohort (MEC): a Pilot****Principal investigator: Prof Chia Kee Seng, National University of Singapore
SCCS hot line: 6478 9608**I agree to provide my NRIC number for the use of this research. Yes No I agree to undergo a health screening which involves taking of up to 9mls (~1 tablespoon) of blood and a urine sample. Yes No I agree to donate up to 31mls (~ 3 tablespoons) of my blood for future studies of diseases and health conditions. Yes No I agree to donate a urine sample for future studies of diseases and health conditions. Yes No I agree to donate my samples for future genetic research of diseases and health conditions. Yes No I agree to allow my stored samples to be used for commercial development Yes No I agree to be re-contacted in 3-5 years time. Yes No

I have been given a chance to ask questions and feel that all of my questions have been answered. I know that participation in this study is my choice and that refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled. In addition, I know that giving a sample for this study is my choice and that refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled. I may also discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled. I have been given a copy of the participant information sheet that explains the use of my information, blood and/or urine in this research, and consent form to keep. I will not have any rights to any commercial benefits that result from this research. I also agree that I will not derive any monetary or other benefits from this research.

I have been informed that any questions pertaining to this research can be directed to SCCS at 6478 9608. Any questions I have regarding my rights as a research subject can be directed to the National University of Singapore-Institutional Review Board (Attn:Mr Chan Tuck Wai 6516 1234).

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* This research has been explained to me in _____ (state language), which I understand, by _____ (name of translator as per NRIC).

Name (as per NRIC) of participant

NRIC (participant)

Signature/ thumb print (participant)

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Day Month Year

I observed the process of consent. The prospective participant read this form, was given the chance to ask questions, appeared to accept the answers, and signed to enroll in the study.

Name (as per NRIC) of consent taker

Signature/ thumb print (consent taker)

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Day Month Year

Name (as per NRIC) of translator

Relationship to participant

Signature/ thumb print (translator)

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Day Month Year

* Include this section if participant is unable to understand English and read any of the translated consent documents available.

CONSENT FORM C**Study title: Re-visiting the Singapore Consortium of Cohort Studies (SCCS) - Multi-ethnic cohort (MEC): a Pilot****Principal investigator: Prof Chia Kee Seng, National University of Singapore
SCCS hot line: 6478 9608**

I agree to undergo an X-ray scan to determine the fat and bone composition in my body for the purpose of this research and future studies.

Yes No

I agree to undergo an X-ray scan to determine the amount of calcified deposits in my coronary arteries for the purpose of this research and future studies.

Yes No

I agree to 13mls of the blood sample donated for future study of diseases and health conditions to be used for the study of human variation in blood lipid and metabolite levels.

Yes No

I have been given a chance to ask questions and feel that all of my questions have been answered. I know that participation in this study is my choice and that refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled. I may also discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled. I have been given a copy of the participant information sheet that explains the use of my information, blood and/or urine in this research, and consent form to keep. I will not have any rights to any commercial benefits that result from this research. I also agree that I will not derive any monetary or other benefits from this research.

I have been informed that any questions pertaining to this research can be directed to SCCS at 6478 9608. Any questions I have regarding my rights as a research subject can be directed to the National University of Singapore-Institutional Review Board (Attn:Mr Chan Tuck Wai 6516 1234).

* This research has been explained to me in _____ (state language), which I understand, by _____ (name of translator as per NRIC).

Name (as per NRIC) of participant

NRIC (participant)

Signature/ thumb print (participant)

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Day Month Year

* Include this section if participant is unable to understand English and read any of the translated consent documents available.

CONSENT FORM C**Study title: Re-visiting the Singapore Consortium of Cohort Studies (SCCS) - Multi-ethnic cohort (MEC): a Pilot**

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Name (as per NRIC) of consent taker

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Signature/ thumb print (consent taker)

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Day Month Year

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Name (as per NRIC) of translator

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Relationship to participant

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Signature/ thumb print (translator)

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Day Month Year