

## PARTICIPANT INFORMATION SHEET

**Study title: Singapore Population Health Studies (SPHS) - Multi-ethnic cohort (MEC)**

**Principal investigator: Prof Chia Kee Seng, Saw Swee Hock School of Public Health, National University of Singapore**

**SPHS hot line: 64789608**

1. You are invited to participate in a research study. This information sheet provides you with information about the research, hereinafter referred to as the “**MEC Study**”. The Principal Investigator (the research doctor or person in charge of this research) or his/her representative will also describe this MEC Study 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?**

2. The purpose of the MEC Study 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.

### **Who can take part in this MEC Study?**

3. Participation is through invitation only. People who can take part in this MEC Study include:

- (a) Singaporeans and permanent residents of Singapore;
- (b) between age 21-75; and
- (c) of Chinese, Malay or Indian ethnic groups.

4. Exclusion criteria:

- (a) Those who refuse audio-recording of the consent taking and interviews for quality control purposes; or
- (b) Those with the following medical conditions or history of such conditions:
  - 1) Mental illness;
  - 2) Cancer;
  - 3) Stroke;
  - 4) Heart diseases; and
  - 5) Kidney failure (i.e. undergoing dialysis, on a catheter or has very high creatinine levels)

5. If you are currently pregnant, you may participate in this study only 3 months after your delivery.

### **What is involved in the research?**

6. *There will be no medicines to take and no experimental treatments to undergo in this MEC Study.*

#### *(a) Interview*

Initially, trained interviewers appointed by the National University of Singapore (“NUS”) will contact you and visit you in your home or at a place which is convenient to you. During this time, you will be interviewed about your health, exercise, use of tobacco and quality of life. It is alright to skip any question you do not want to answer, except for your NRIC number; which is essential for participation and re-contact. The questionnaire will take approximately 1 hour to complete. The interview information will be separated from your name, NRIC and contact details and entered into a database for research. With your permission, the interviewer shall audio-record the interview for quality control and training purposes. The audio file will be stored in a database separate from the research database for at least 2 years beyond the completion of the recruitment for this MEC Study in March 2016.

#### *(b) Basic Health screening*

You will be asked and given an appointment to attend a health screening at one of our health screening sites which may be at SATA Commhealth Medical Centre (Woodlands Civic Plaza), Bras Basah Complex (231 Bain Street, S180231) or NUS (MD1 12 Science Drive 2, S117549). Our research operations staff will arrange an appointment with you. If you wish to provide a fasting sample for your blood tests, you will need 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 any medical conditions (e.g. diabetes) and/or on any medication, please consult your doctor before fasting. During the health screening which will take about 1.5hr, our research assistants will:

- 1) measure your weight, height, waist and hip circumferences, and the skinfold thickness of your arm and trunk;

- 2) measure the blood pressure at your ankle, arm and near your heart using non-invasive measuring devices;
- 3) measure the strength of your hand grip;
- 4) use an instrument to test the functional status of the nerves supplying your feet.
- 5) obtain samples of blood (up to 20mls or 2 tablespoons) and urine for future Public Health Research (as described below);
- 6) obtain samples of blood (up to 9mls or about 1 tablespoon) for sugar, cholesterol and creatinine tests, and urine for protein level measurement to be used for the MEC Study; and/or
- 7) use an instrument (ECG) to study the rhythm of your heart. You will be asked to remove your top and sticky pads called electrodes will be stuck to your chest, arms and legs during this test.

*(c) Re-contact*

You may be contacted later to obtain additional health information or to clarify uncertainties regarding the information collected. SPHS researchers and/or an external agency appointed by NUS will also contact you again in 3-5 years to conduct further follow-ups on this MEC Study and/or future Public Health Research (as described below). We will ask you for your consent for the Saw Swee Hock School of Public Health to inform you of news about its research studies or invite you to take part in other Public Health Research (as described below) conducted by the Saw Swee Hock School of Public Health. Even if you have participated in this MEC Study, you may refuse to participate in later studies.

*(d) Research using Medical Records*

We will also ask for your consent to allow us to obtain relevant information about your health status or medical condition with national registries of medical conditions or living status, or your medical records, either for this MEC Study or future Public Health Research (as described below). This information is very useful for us to study the effects of lifestyle on diseases.

## **Future Research on Public Health**

7. Public health is about assisting communities stay healthy through the prevention of disease and other health conditions, and the promotion of health behaviours. Public health professionals conduct research to identify social, environmental, biological and genetic factors which affect one's health or contribute to the spread of disease in a population. By collecting and studying such health related data, researchers can develop educational programs or propose health policies to improve the health and quality of life of communities (collectively referred to as "**Public Health Research**").

## **Why should I donate blood and urine for storage and future Public Health Research?**

8. 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 from Singapore and/or other countries in Public Health 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.

9. If you agree, we will draw about 29mls (about 3 tablespoons) of blood from a vein in your arm, use 9mls for the basic health screening and store the remaining 20mls, and store 6mls of your urine sample provided for the basic health screening. Your blood and urine samples collected for future Public Health Research will be stored in Singapore at the National University Health System (NUHS) Tissue Repository for as long as they are necessary or depleted.

10. The stored samples of blood and urine may be used for future Public Health Research in Singapore or overseas by NUS and/or NUS' collaborators. Any researcher, including those that are part of the present MEC Study, 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?**

11. 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 in Singapore or overseas. 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?**

12. 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.

13. 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?**

14. 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.

15. 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.

### **Is there any cost or payments involved in the research trial?**

16. It does not cost you anything to take part in this MEC Study and you will not be charged for any tests. You will not be paid for participation in this MEC Study or future Public Health Research. You will be reimbursed for your time and effort as follows: (a) SGD \$15 upon the completion of the interview; and (b) SGD\$50 upon completing the optional health screening. This paragraph does not waive any of your legal rights.

17. If you wish to donate your reimbursement to a charity instead, we can assist in transferring your reimbursement to the Ang Mo Kio-Thye Hua Kwan Hospital (<http://www.amkh.com.sg>), at your request. The hospital will mail to you a receipt of donation after a few months.

### **Will I find out results of the research?**

18. 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 levels;
- 2) blood pressure;
- 3) urine protein level;
- 4) body mass index; and
- 5) ECG result

19. 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. However, a referral letter will be provided to you to see your doctor should any abnormal results be found.

20. Neither you nor your doctor will receive the results of other future Public Health 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 future Public Health Research using your samples may not be ready for the immediate future.

### **Will researchers have access to my medical records?**

21. Certain information from your medical records may be required for interpreting research results, e.g. age, gender, medical history and details of present illness. With your permission, only SPHS operations staff will have

access to these medical records to obtain the relevant data. The data will be stored in SPHS databases and only certain approved researchers will be permitted access to the data.

### **How will my privacy be protected?**

22. 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 (name, NRIC, contact numbers and addresses). Instead, these will be replaced by code numbers for research in SPHS databases for at least 10 years. 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 IRB.

23. Sometimes, our research requires sharing of the data collected with other researchers who have an important scientific question that our data could be used to answer. Sometimes, we need to combine data with other research groups in order to answer scientific questions that individual studies alone would not be able to answer. We will only share data without personal identifiers and that is relevant to answering the scientific question, and only after an IRB has approved the research proposal.

24. Data from the interview on quality of life will be stored in an international database, so that other researchers can study the quality of life of different populations, or help improve the quality of life questionnaire. This database is maintained by the EuroQol Research Foundation ([www.EuroQol.org](http://www.EuroQol.org)), an organisation that created the quality of life questionnaire that is now used in many countries.

25. When results of this MEC Study or future Public Health Research are reported in medical journals or at scientific meetings or used for future Public Health Research, the people who take part are not named and identified. However, records from this research 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?**

26. Once you have read this Participant Information Sheet, 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 MEC Study and future Public Health 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'.

### **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?**

27. You can withdraw from the MEC Study and future Public Health Research at any time without giving reasons. You can notify us by a call (6478 9608) or email ([sphs@nus.edu.sg](mailto:sphs@nus.edu.sg)) and we will (a) terminate your further participation in the MEC Study and/or future Public Health Research; and/or (b) destroy any unused blood and/or urine that you have already donated and data that have not been analysed. 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?**

28. This research is conducted by the Centre for Molecular Epidemiology, Saw Swee Hock School of Public Health at NUS. **The principal investigator (person in charge of this research) is Professor Chia Kee Seng.**

29. If you have any questions about:  
 (a) any research-related matters and in the event of research-related injuries — call the SPHS hotline at 6478 9608 or email to [sphs@nus.edu.sg](mailto:sphs@nus.edu.sg); or  
 (b) 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.

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**Principal investigator: Prof Chia Kee Seng, Saw Swee Hock School of Public Health, National University of Singapore**

Please note that the defined terms used in this document are as stated in the Information Sheet provided to the participant.

- |  | YES                      | NO                       |
|--|--------------------------|--------------------------|
| 1. I agree to provide my name, NRIC number, contact number(s) and address to the National University of Singapore (“NUS”) (through interviewers appointed by NUS) for the purpose of this MEC Study.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. I agree to participate in the interview about my social background, health, medical history and lifestyle for this MEC Study.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. I understand that the interview will be audio-recorded for quality control and training purposes.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. I agree to allow the de-identified data of my quality of life survey to be shared on an international database.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. I agree to allow relevant information about my health status and medical condition to be obtained by the Saw Swee Hock School of Public Health from the relevant national registries or my medical records, for the purposes of this MEC Study.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. I agree to allow relevant information about my health status and medical condition to be obtained by the Saw Swee Hock School of Public Health from the relevant national registries or my medical records to be used by NUS and/or NUS’ collaborators for future Public Health Research. | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. I agree to undergo a health screening which involves taking of up to 9mls (~1 tablespoon) of blood and a urine sample for this MEC study.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. I agree to donate up to 20mls (~ 2 tablespoons) of my blood for future Public Health Research in Singapore or overseas by NUS and/or NUS’ collaborators.  | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. I agree to donate a urine sample for future Public Health Research in Singapore or overseas by NUS and/or NUS’ collaborators.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. I agree to donate my blood sample for future genetic research by NUS and/or NUS’ collaborators.  | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. I agree to allow my stored samples of blood and urine to be used for commercial development of diagnostic or treatment procedures by commercial entities in Singapore or overseas and I understand that I will not have any rights to any commercial benefits resulting from it.         | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. I agree to be re-contacted in 3-5 years’ time by NUS and/or its appointed external agent for the conduct of further follow-up in relation to this MEC Study or in relation to future Public Health Research.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. I agree to receive news about the research conducted by the Saw Swee Hock School of Public Health and invitations to participate in future Public Health Research by the Saw Swee Hock School of Public Health.  | <input type="checkbox"/> | <input type="checkbox"/> |

\* 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

\_\_\_\_\_  
Signature/ thumb print (participant)

\_\_\_\_\_  
NRIC (participant)

\_\_\_\_\_  
Date of Consent  
Day (DD) Month (MM) Year (YYYY)

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)

\_\_\_\_\_  
Date of Consent  
Day (DD) Month (MM) Year (YYYY)

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

\_\_\_\_\_

\_\_\_\_\_  
Name (as per NRIC) of translator

\_\_\_\_\_  
Signature/ thumb print (translator)

\_\_\_\_\_  
Relationship to participant

\_\_\_\_\_  
Date of Consent  
Day (DD) Month (MM) Year (YYYY)

By signing this Consent Form, I agree to take part in this MEC Study. I may discontinue participation in the MEC Study or future Public Health Research at any time without penalty or loss of benefits. I have received a copy of the participant information sheet that explains the use of my information and my blood and urine samples in this MEC Study and future Public Health Research. I have read and understood the contents.