PARTICIPANT INFORMATION SHEET

Study title: Singapore Population Health Studies – Singapore Health 2012
Principal investigator: Prof Chia Kee Seng, Saw Swee Hock School of Public Health, National University of Singapore
Hotline: 6478 9608

You are invited to participate in a research study. 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 Singapore Population Health Studies (SPHS) – Singapore Health 2012 (SH2012) is carried out by the Saw Swee Hock School of Public Health, NUS and is supported by the Ministry of Health (MOH). It aims to assess the health status, including common chronic diseases such as high blood pressure and diabetes, and health-related lifestyle factors of Singaporeans. The SH2012 is an important study as the results will enable the School and MOH to observe, over time, how well Singaporeans are progressing in their efforts to improve their health. The study will also help the School and MOH to review the effectiveness of existing disease control policies and to plan new programmes to improve the health of Singaporeans.

Who can take part in this research?

Singaporeans or Singapore permanent residents who are 18 to 79 years old will be invited to participate in the SH2012.

This study will exclude persons who:

1) are pregnant or have delivered within the past three months;
2) have severe mental retardation or major mental illness (including acute schizophrenia and dementia);
3) had stroke or injury resulting in the loss of speech;
4) are bedridden or wheelchair bound; and
5) are less than 21 years old and for whom the parent or legal guardian is not available to provide consent.

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 convenient to you. They will interview you about your health, lifestyle, diet, exercise, your use of tobacco, alcohol and medicines, and your use of certain types of health services. It is alright to skip any question you do not want to answer, except NRIC; which is essential for recruitment and re-contact. The interview will take approximately 1.5hr and may be audio-recorded. The interview information will be separated from your name, NRIC and contact details and entered into a database for research. The recording files will be stored separately and indefinitely for purposes of quality control and training. You will then be asked to attend a health screening on a separate day.

- *Health Screening*

The health screening will be conducted at one of our health screening sites which may be at a SATA Commhealth Medical Centre or at Cheng San Community Club, 6 Ang Mo Kio Street 53, Singapore 569205. Our research staff will arrange an appointment for you to attend the health screening at a site convenient for you. You will be asked to fast (no food or drinks, except plain water) 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 visit which will take about 3hr, 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 both your arms;
3) use an instrument to determine if you have loss of hearing;
4) obtain blood sample for sugar, cholesterol and creatinine tests, and urine for protein level measurement;
5) obtain blood, DNA and urine samples for long-term storage for future research use (see the next section) *[Note : The long-term storage of DNA sample to conduct genetic studies is <u>optional</u>. You are still eligible to participate in this study if you refuse to consent for the DNA storage]* ;
6) use an instrument (ECG) 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; and
7) interview you about sun exposure, quality of sleep, weight and mental health.

- *Re-contact*

You may be contacted later to obtain additional health information or to clarify uncertainties regarding the information collected. SPHS researchers will also contact you again in 3-5 years to conduct further follow-ups or related studies on major health conditions. Even if you have participated in this revisit, you may refuse to participate in later revisits or other 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 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.

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

Researchers at NUS and other healthcare/ research institutions are trying to learn more about diseases. Your blood and urine can be used to study different diseases in addition to the common chronic diseases of interest in this particular study. Blood and urine contain markers that may be indicative of certain conditions of the body. Blood is also a source of DNA, the genetic material that distinguishes different people from each other. The storage of DNA derived from blood will allow future studies of genes that will help researchers understand how certain diseases develop. 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 32mls (about 3.5 tablespoons) of blood from a vein in your arm and/or collect about 20mls of urine. Your samples (about 23 mls of blood and 6mls of urine) will be stored at the National University Health System (NUHS) Tissue Repository. They can be used for future research for as long as they are available.

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.

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.

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 $80 only if you complete all the interviews and attended the health screening. If you are not able to come to any of our health screening sites due to physical disability and have no one to help you with the travel, we may arrange for a health screening facility set up inside a bus to go to your neighbourhood. You will be reimbursed $50 for the completion of the interviews and health screening on the bus. If you wish only to take part in the interview of about 1.5hr long, you will receive a token of $20. 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) hearing loss; and
6) ECG

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 are detected by the tests conducted.

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 SPHS 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 indefinitely in SPHS 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 (name, NRIC, contact numbers and addresses). Instead, these will be replaced by code numbers for research and indefinite storage in SPHS databases. 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 Participation 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 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’.

If you are below 21 years old, your parent’s or legal guardian’s consent for your participation will also be required and he/she would also need to sign on the consent form.

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 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?
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**.

If you have any questions about:

1) this research — call the study hotline at 6478 9608 or send an email to sphs@nus.edu.sg; 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

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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, well- being, diet and exercise; my use of tobacco, alcohol and medicines; and use of health services.	Yes ☐	No ☐
I agree to the audio-recording of the interview for quality control and training Purposes.	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 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 23mls (~ 2.5 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 DNA samples for future genetic research.	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 to conduct further follow-ups or related studies of major health conditions.	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 SPHS 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)	*Day Month Year*

[For legal guardian of participant aged 18 to 20] I hereby, as the legal guardian, consent for the participant named above to participate in this study.

Name (as per NRIC) of Parent/Legal Guardian	*NRIC of Parent/Legal Guardian*
Signature/ thumb print (Parent/Legal Guardian)	*Relationship to participant*
	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	*NRIC (consent taker)*
Signature/ thumb print (consent taker)	*Day Month Year*

Name (as per NRIC) of translator	*Relationship to participant*
Signature/ thumb print (translator)	*Day Month Year*

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