PARTICIPANT INFORMATION SHEET

Study title: Singapore Population Health Studies (SPHS) – Singapore Health 2 (SH2)
Principal investigator: Assistant Professor Lim Wei-Yen, Saw Swee Hock School of Public Health, National University of Singapore
SPHS hot line: 64789608

You are invited to participate in a research study. This information sheet provides you with information about the research. The Principal Investigator (the person in charge of this research) or his 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 2 (SH2) 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, mental wellness and health-related lifestyle factors of Singaporeans. It also aims to estimate the proportion of the Singapore population that has latent or inactive tuberculosis (TB)*. The SH2 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.

** A person who has inactive TB is not sick, does not have TB symptoms and is not infectious. TB disease will develop in about 1 in 10 persons with inactive TB.*

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 SH2. This study will exclude persons who:

1) are pregnant or have delivered within the past 3 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;
5) are residing in institutions, e.g. nursing homes; and
6) 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*

A trained interviewer 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, lifestyle, quality of life and use 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 questionnaire will take approximately 1.5 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 study in August 2014.

- *Basic Health screening*

You will be asked and given an appointment to attend a health screening at one of our health screening sites: a SATA Commhealth Medical Centre, Cheng San Community Club (6 Ang Mo Kio Street 53, S569205) or at Bras Basah Complex (231 Bain Street, S180231). 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 a medical condition (e.g. diabetes) or/and on any medication, please consult the doctor before fasting. During the health screening which will take about 2hrs, our research assistants will:

1) measure your weight, height, waist and hip circumferences, and the skinfold thickness of your arm, back and waist;
2) measure your blood pressure;
3) obtain a sample of blood and urine from you:
    a) about 12mls (or about 1 tablespoon) of blood to test for sugar, cholesterol, creatinine and past exposure to TB bacteria, and urine for protein level measurement;
    b) up to 20mls (or 2 tablespoons) of blood and 10mls urine to be stored for future studies and genetic research;

4) conduct a hearing loss test; and
5) perform an electrocardiogram (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.

- *Physical Activity Tracking*

You may also be invited to take part in a physical activity tracking part of this study. If you agree, you will need to wear an accelerometer (a small, portable device that measures your physical movement) around your waist for 7 days. It is like a pedometer that counts the number of steps you take. It does not record any other information, e.g. type of activity, location, heart rate. A summary of your physical activity will be given to you within 8 weeks when you return the accelerometer to us. Individuals who need another person's assistance, a walker or wheelchair to move about will be excluded from this part of the study.

- *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. 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 research studies conducted by the School. Even if you have participated in this study, you may refuse to participate in later studies.

- *Research using Medical Records*

We will also ask for your consent to allow us to check on your health status with national registries of medical conditions or living status, or your medical records in the polyclinics or hospitals, 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?

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.

Samples will be stored at the National University Health System (NUHS) Tissue Repository for as long as they are available. Any researcher, including those that are part of the present research, who would like to use these 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. 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.

Is 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 a $20 token upon the completion of the interview, a $20 token for completing the physical activity tracking and $50 upon completing the health screening.

If you wish to donate your $50 reimbursement to a charity, staff at the health screening centre can assist in transferring your reimbursement to the Ang Mo Kio-Thye Hua Kwan Hospital (http://www.amkh.com.sg). The hospital will mail to you a receipt of donation after a few months.

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) hearing loss;
5) body mass index;
6) ECG result; and
7) TB blood test result.

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.

Neither you nor your doctor will receive the results of other research done with your donated samples. Only anonymised samples will be used for analysis and results from research using your samples may not be ready in the immediate future.

Will researchers have access to my medical records?
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.

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 stored 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 that oversees the ethical aspects of the research.

Data from the quality of life interview (without any identifying information such as names, IC numbers or addresses) from all the participants of this study will be stored in an international database of the EuroQol Group (www.EuroQol.org) who created the questionnaire now used in many countries. Sharing the data in the international database will allow many researchers to use the data, either for research on quality of life of different populations or to improve the questionnaire. We will not share any information that may identify you.

Sometimes, our research requires sharing of the data collected with other researchers. This can happen when other research groups have an important scientific question that our data could be used to answer. In other cases, we may choose to add the data collected from our study to data collected from other research studies so that the amount of data we have is greater and can allow us to answer scientific questions that individual studies alone would not be able to answer. In these cases, we will only send data that is relevant to answering the scientific question, and in *all* cases, *no* data that could identify you as a participant (such as name, IC number, addresses or contact information) would be sent. We will also obtain approval from an IRB to check that the study proposed is ethically reasonable and acceptable before proceeding to share that data.

Only de-identified and grouped data will be used in reporting the results of this research in medical journals or at scientific meetings. 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?
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 research. The decision to participate is up to you.

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 SPHS unit of the Saw Swee Hock School of Public Health at NUS. **The principal investigator (person in charge of this research) is Assistant Professor Lim Wei-Yen**.

If you have any questions about:

1) any research-related matters and in the event of research-related injuries — call the SPHS 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

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1.	I agree to provide my NRIC number for the use of this research.	☐ Yes	☐ No
2.	I agree to participate in the survey about my health, lifestyle, exercise, quality of life and use of health services.	☐ Yes	☐ No
3.	I agree to allow the interview to be audio-recorded for quality control and training purposes.	☐ Yes	☐ No
4.	I agree to allow the de-identified data of my quality of life survey to be shared on an international database.	☐ Yes	☐ No
5.	I agree to participate in the physical activity tracking for 1 week.	☐ Yes	☐ No
6.	I agree to allow relevant information on my health status and medical condition to be gathered from national registries or my medical records for this study.	☐ Yes	☐ No
7.	I agree to allow relevant information on my health status and medical condition to be gathered from national registries or my medical records for future research.	☐ Yes	☐ No
8.	I agree to undergo a health screening which involves taking of up to 12mls (~1 tablespoon) of blood and a urine sample.	☐ Yes	☐ No
9.	I agree to donate up to 20mls (~ 2 tablespoons) of my blood for future studies of diseases and health conditions, and genetic research.	☐ Yes	☐ No
10.	I agree to donate a urine sample for future studies of diseases and health conditions.	☐ Yes	☐ No
11.	I agree to allow my stored samples to be used for commercial development and I understand that I will not have any rights to any commercial benefits resulting from it.	☐ Yes	☐ No
12.	I agree to be re-contacted in 3-5 years' time to conduct further follow-up or related studies of major health conditions.	☐ Yes	☐ No
13.	I agree to receive news about research and invitation to participate in other research studies by the Saw Swee Hock School of Public Health.	☐ 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 or 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 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.

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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).

* 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* *Date of consent*

[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	
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.*