PARTICIPANT INFORMATION SHEET

Study title: Singapore Population Health Studies (SPHS) - Multiethnic and Diabetic Cohorts Revisit
Principal investigator: Assoc. Prof Rob Martinus van Dam, Saw Swee Hock School of Public Health, National University of Singapore
SPHS 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 Saw Swee Hock School of Public Health has identified several existing cohorts for revisit as an important part of its Singapore Population Health Studies (SPHS). These cohorts are: the Singapore Consortium of Cohort Studies (SCCS)-Multiethnic Cohort (MEC) and Diabetic Cohort (DC), the Singapore Cardiovascular Cohort Study (SCCS2) and the Singapore Prospective Study Project (SP2).

The purpose of this first revisit is to find out:
1) how factors like diet, exercise and smoking etc. are related to heart disease, diabetes, stroke and other common diseases in Singapore and how these important factors have changed since the last survey and health screening; and
2) the health care costs related to obesity and related chronic metabolic diseases (such as diabetes) and its burden to patients. This information would help us to recommend better ways of allocating health prevention and care resources.

Who can take part in this research?
Participants of the MEC, DC, SCCS2 and SP2 will be invited to take part in this revisit.

Participants who have developed a severe mental illness (e.g. schizophrenia, psychotic depression or severe dementia) or who refuse audio-recording of interviews for quality control and training purposes will be excluded.

What is involved in the research?
There will be no medicines to take and no experimental treatments to undergo in this research.

- *Interview*

Initially, a trained interviewer will contact you and visit you in your home or at a place which is convenient to you. You will be interviewed about your health, quality of life, diet, exercise, 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 participation and re-contact. The interview will take about 1.5 hr. 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 Mar 2017.

- *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 Bras Basah Complex (231 Bain Street, S180231) or NUS (MD1 12 Science Drive 2, S117549). Our research staff will arrange an appointment for you to attend the health screening. You will be asked to fast (no food or drinks, except plain water) for 10-12hr prior to the health screening visit. 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 1.5-2hr, our research assistants will:
1) measure your weight, height, waist and hip circumferences;
2) measure the blood pressure at your ankle and arm;
3) measure the strength of your hand grip;
4) use an instrument to determine the functional status of the nerves supplying your feet.
5) obtain samples of blood (up to 23mls or about 2.5 tablespoon) and urine for future studies and genetic research;
6) obtain blood sample (up to 9mls or about 1 tablespoon) for sugar, cholesterol and creatinine tests, and urine for protein level measurement;
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; and/or
8) assess your ability to get up from a chair and walk a short distance.

- *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 revisit, you may refuse to participate in later revisits or other studies.

- *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 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.

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) collected for future research will be stored at the National University Health System (NUHS) Tissue Repository for as long as they are necessary or depleted.

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 not be paid for participation in this research. You will be reimbursed for your time and effort, $15 upon the completion of the home interview, and $50 upon completing the health screening. 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 levels;
2) blood pressure;
3) urine protein level;
4) body mass index; and
5) 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 be found.

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 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 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 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.

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.

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), an organization that created the quality of life questionnaire that is now used in many countries.

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 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. 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?
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 Saw Swee Hock School of Public Health at NUS. **The principal investigator (person in charge of this research) is Associate Professor Rob Martinus van Dam**.

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 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.

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Principal investigator: A/Prof Rob Martinus van Dam, 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 NRIC number for the use of this research.	☐	☐
2.	I agree to participate in the survey about my health, quality of life, diet and exercise, and my use of tobacco, alcohol and medicines.	☐	☐
3.	I understand that the interview will be audio-recorded for quality control and training purposes.	☐	☐
4.	I agree to allow the de-identified data of my quality of life survey to be shared on an international database.	☐	☐
5.	I agree to allow relevant information about my health status and medical condition to be gathered from the relevant national registries or my medical records for this study.	☐	☐
6.	I agree to allow relevant information about my health status and medical condition to be gathered from the relevant national registries or my medical records for future research.	☐	☐
7.	I agree to undergo a health screening which involves taking of up to 9mls (~1 tablespoon) of blood and a urine sample.	☐	☐
8.	I agree to donate up to 23mls (~ 2.5 tablespoons) of my blood for future studies of diseases and health conditions.	☐	☐
9.	I agree to donate a urine sample for future studies of diseases and health conditions.	☐	☐
10.	I agree to donate my blood samples for future genetic research.	☐	☐
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.	☐	☐
12.	I agree to be re-contacted in 3-5 years' time to conduct further follow-up or related studies of major health conditions.	☐	☐
13.	I agree to receive news about the research and invitations to participate in other research studies by the Saw Swee Hock School of Public Health.	☐	☐

By signing this Consent Form, I agree to take part in this study. I may also discontinue participation 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 and future research. I have read and understood the contents.

* 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)*	