PARTICIPANT INFORMATION SHEET

Study title: Singapore Population Health Studies (SPHS) – First Follow-Up
Principal investigator: Associate Professor Rob Martinus van Dam, 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. 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 about?

2. The purpose of the SPHS – First Follow-up study is to follow-up on the participants of SPHS. The research will continue to find out 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 research?

3. Participants of the SPHS will be invited to take part. We will exclude participants who refuse audio-recording of the consent taking and interview or has a severe mental illness and thus unable to give consent personally.

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

What is involved in this research?

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

Interview

6. First, a trained interviewer appointed by the National University of Singapore (“NUS”) will contact you to arrange a face-to-face interview about your health, exercise, smoking and drinking and quality of life. The interview will take about 1.5hr to complete. It is alright to skip any question you do not want to answer. The interview will be audio-recorded for quality control and training purposes, and the audio file will be stored for at least 2 years.

Health screening

7. After the interview, you will be offered an option to attend a health screening. We can arrange an appointment for you to attend the health screening at NUS (MD1, 12 Science Drive 2, S117549) or Bras Basah Complex (231 Bain Street, S180231). You will need to fast from 10 pm the night before or for 10-12hr prior to the health screening appointment time for the blood tests. If you have any concerns about fasting affecting your medical condition or medication, please consult your doctor before fasting. The health screening will take about 1.5-2hr and may include the following procedures:
   1) Measurement of your weight, height, waist and hip;
   2) Measurement of the blood pressure, at the ankle and arm;
   3) Measurement of the strength of your hand grip;
   4) Test your eyesight;
   5) Test the functional status of the nerves supplying your feet;
   6) Obtain a blood sample from your arm
      (i) up to 9mls (or about 1 tablespoon) for sugar, cholesterol and creatinine tests
      (ii) up to 20mls (or 2 tablespoons) to be stored for future Public Health Research*
7) Obtain a urine sample to
   (i) Test the protein level
   (ii) Store up to 6mls (about half a tablespoon) for future Public Health Research*
8) Record the rhythm of your heart (electrocardiogram or ECG). 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:
9) Assess your walking and balancing; and/or
10) Assess your lung function or a community environment survey.

Physical Activity Tracking

8. You may be selected to undergo a 9-day recording of your physical activity, outdoor time
   and movement patterns. If you agree, you will need to wear an accelerometer (a small, portable
   device that measures your physical activity) around your waist for 9 days during all waking hours.
   You will also need to download a free mobile app which will ask you up to 10-12 questions daily
   about your activity and commuting and automatically collect your location data (coordinates) every
   10min over the same period. You will be given a unique code to access the app so that the data
   collected will be immediately de-identified. While wearing the accelerometer, the location function
   of your mobile phone has to be turned on and the phone carried with you. After the 9-day period,
   you will need to return the accelerometer to the study team when you attend your health screening.

9. Individuals who have mobility issues, will not be attending the health screening, do not carry
   a smart phone or do not have sufficient mobile data will be excluded from this part of the study. The
   data collected from this study component will allow researchers to study how activity and movement
   patterns, outdoor time and the environment relate to health.

Re-contact

10. We may contact you later to obtain additional health information or to verify information
    already collected. We may contact you again in 3-5 years to invite you to take part in the second
    SPHS follow-up. We may also reach you to inform you of news about our research studies or invite
    you to take part in other Public Health Research*.

11. One of our biggest challenges in research like this one is following up on our participants
    who have changed their contact details. We may apply to the Ministry of Health (MOH) or Ministry
    of Home Affairs to request your most up-to-date contact information.

Research using Health Records

12. You may have health records with the National Electronic Health Records, with health care
    institutions or in our national registries. Certain information from your health records is important for
    us to study how diseases become worse, e.g. stage of disease, frequency of hospital visits and type
    of medical treatment etc. We would like to have your consent to allow us to collect the data from your
    health records that are useful for this research and future Public Health Research*. Only certain
    approved researchers will have access to these data. These data will be de-identified and stored in
    the NUS database for research use.

*Future Research on Public Health

13. 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”).

What will be done with my samples?
14. Up to 29mls (about 3 tablespoons) of blood will be taken from a vein in your arm during the health screening. 20mls of the blood sample and 6mls of the urine sample will be stored in the tissue repositories of the National University Hospital and the NUS Saw Swee Hock School of Public Health in Singapore. These samples will be stored for as long as they are necessary or until they are used up for Public Health Research.

15. Your blood and urine can be used to study different diseases. Blood contains markers that tell us about certain conditions of the body, e.g. cholesterol and sugar levels. 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.

16. The stored samples may be used for future Public Health Research in Singapore or overseas by NUS and/or NUS’ collaborators. NUS may require its collaborators to cover the costs of packaging and delivery of the samples, but NUS will not sell your samples to anyone for profit. Your samples will not be provided for biomedical research that involves human-animal combinations.

17. Your donated samples may contribute to research discoveries that enable commercial companies or institutions to develop new treatments or diagnostic procedures. The commercial development of those products may bring profits to the companies and some of the profits may be paid back to the researchers and the institutions involved in that research.

Will I benefit from the research and/or research done on my samples?

18. Your donation of blood and/or urine is regarded as wholly voluntary and as a gift. 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 data derived from it. However, the results of research may benefit populations in the future.

What are the risks of taking part in the research?

19. 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. If you follow the directions of our study staff and are physically injured due to the procedure of this study, NUS will pay the medical expenses for the treatment of that injury.

20. 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.

What are the costs involved in taking part?

21. All the tests mentioned above will be performed at no charge to you. You will be reimbursed for your time and effort, SGD $15 upon the completion of the interview and SGD$50 upon completing the health screening.

22. If you complete the physical activity tracking study component and attend the health screening, you will be reimbursed SGD$20 which will also cover the cost of your mobile data usage during the 9-day period.

Will I find out results of the research?

23. 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 pressure;
2) body mass index (BMI);
3) blood creatinine, sugar and cholesterol levels;
4) urine protein level;
5) vision; and
6) ECG result.

24. You should feel free to discuss these results with your own doctor. The data collection and procedures are only being performed for the purposes of the research and is not part of any standard care or treatment. However, a referral letter will be provided to you to see your doctor should any abnormal results be found.

25. In the event that further analyses on your data and/or samples in this research produce findings that may be of clinical importance to you and you have indicated in the Consent Form that you want to be informed of the findings, we will attempt to contact you by phone or mail. We will not share any research results with your doctor. However, it may take many years to have results from the research.

How will my privacy be protected?

26. Information collected for this study will be kept confidential. Your health information will be de-identified (i.e. separated from your name, NRIC, contact numbers and addresses), coded and stored in the NUS research database for at least 10 years. Your samples will also be stored in de-identified and coded form. Researchers, local or overseas, including those who are NUS’ collaborators, will only analyse the information or samples in their de-identified and coded form. Your personal data will not be shown when we present the results of this research or future Public Health Research in publications or scientific meetings.

27. It is possible to retrace the link between the personal data and the codes by a decoding step. This decoding only takes place under special circumstances (such as when we have permission to re-contact you or in the event of a national emergency) and approval needs to be given by an Institutional Review Board (IRB).

28. Regulatory authorities (e.g. MOH) may inspect the original research records to check study procedures and data, but none of the personal data will be made public.

Can I refuse to take part? Can I change my mind after I have signed or donated my samples?

29. Your decision to take part in this research is voluntary and completely up to you.

30. You can also withdraw from this research 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) and we will: (1) terminate your further participation in this research and/or future Public Health Research; and/or (2) 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.

Whom should I call if I have questions or problems?

31. 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.

32. 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 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: Dr Chan Tuck Wai) at 6516 1234.
CONSENT FORM

Study title: Singapore Population Health Studies (SPHS) – First Follow-Up
Principal investigator: Associate Professor 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.

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

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<td><strong>1.</strong> I agree to provide my name, NRIC number, contact number(s) and address to the National University of Singapore (&quot;NUS&quot;) (through interviewers appointed by NUS) for the purpose of this research.</td>
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<td><strong>2.</strong> I agree to participate in the interview about my social background, health, medical history and lifestyle for this research.</td>
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<td><strong>3.</strong> I understand that the interview will be audio-recorded for quality control and training purposes.</td>
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<td><strong>4.</strong> I agree to allow the Saw Swee Hock School of Public Health to obtain information about my health from the national registries or my health records for the purposes of this research.</td>
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<td><strong>5.</strong> I agree to allow the Saw Swee Hock School of Public Health to obtain information about my health from the national registries or my health records to be used by NUS and/or NUS’ collaborators for future Public Health Research.</td>
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<td><strong>6.</strong> I agree to undergo a health screening which involves taking of up to 9mls (~1 tablespoon) of blood and a urine sample for this research.</td>
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<td><strong>7.</strong> 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.</td>
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<td><strong>8.</strong> I agree to donate a urine sample for future Public Health Research in Singapore or overseas by NUS and/or NUS’ collaborators.</td>
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<td><strong>9.</strong> I agree to donate my blood sample for future genetic research by NUS and/or NUS’ collaborators.</td>
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<td><strong>10.</strong> I wish to be notified of clinically important findings from this research on my data and/or samples.</td>
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<td><strong>11.</strong> 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.</td>
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<td><strong>12.</strong> I agree to be re-contacted in 3-5 years’ time by the Saw Swee Hock School of Public Health for future follow-up related to this research. The School may request my most recent contact details from the relevant ministry in order to re-contact me.</td>
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<td><strong>13.</strong> I agree to receive from the Saw Swee Hock School of Public Health news about its research and invitations to participate in future Public Health Research.</td>
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By signing this Consent Form, I agree to take part in this Research. I may discontinue participation in the Research 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 Research and future Public Health Research. I have read and understood the contents.

Signature/ thumb print (participant)

Name (as per NRIC) of participant

Signature/ thumb print (participant)  Date of Consent

NRIC (participant)  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.

Signature/ thumb print (consent taker)  Date of Consent

Name (as per NRIC) of consent taker

Signature/ thumb print (consent taker)  Date of Consent

Name (as per NRIC) of witness

Signature/ thumb print (witness)  Date of Consent

Day (DD)  Month (MM)  Year (YYYY)

I certify to the best of my knowledge that the participant signing this consent form has given consent voluntarily.

Annex D, IRB v3, 08 Jun 2017