

## PARTICIPANT INFORMATION SHEET

You are invited to participate in a research study. This information sheet provides you with information about the study. The Principal Investigator (the person in charge of this research) or his/her representative will also describe this 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.

### 1. Protocol title

This study is known as the "Singapore Population Health Studies (SPHS) – First Follow-up".

### 2. Principal Investigator and co-investigator(s)

**Principal Investigator (PI):** Professor Rob Martinus van Dam<sup>1</sup>

**Co-investigators:**

Professor Chia Kee Seng<sup>1</sup>

Dr Mythily Subramaniam<sup>2</sup>

Dr Kavita Venkataraman<sup>1</sup>

Professor Tai E Shyong<sup>1</sup>

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### 3. Whom should I call if I have any questions or problems?

Please contact the SPHS operations team at telephone **6478 9608** [Mondays to Fridays from 8.30am to 5.30pm, except public holidays] and email [sphs@nus.edu.sg](mailto:sphs@nus.edu.sg) for all study-related matters and in the event of study-related injuries.

This study has undergone an ethics review by the National University of Singapore Institutional Review Board (NUS-IRB). For an independent opinion regarding the ethics of this study and the rights of participants, or if you have complaints about the study, you may contact a staff member of the NUS-IRB at telephone (+65) 6516 1234 [Mondays to Thursdays from 8.30am to 6pm, and Fridays from 8.30am to 5.30pm, except public holidays] or email at [irb@nus.edu.sg](mailto:irb@nus.edu.sg).

### 4. What is the nature and purpose of this biomedical research?

This study is investigational in nature and we hope to discover new information which may contribute to scientific and public health knowledge. The data collection and procedures are only being performed for the purposes of the study and are not part of any standard care or treatment.

The purpose of the SPHS – First Follow-up study is to follow-up on the participants of the Singapore Population Health Studies (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.

### 5. Who can participate in the research? What is the expected duration of my participation? What is the duration of this research?

We would like to invite those who meet these criteria:

- 1) Participants of the SPHS; and
- 2) Aged 21 or older.

The following persons will be excluded from this study:

- 1) Those who refuse audio-recording of the consent taking and face-to-face interview.
- 2) Those who refuse to provide their NRIC numbers for the purpose of this study.
- 3) Those who have a severe mental condition and are thus unable to give consent independently.

Participants who are currently pregnant may begin their survey 3 months after giving birth.

This is a long-term research on chronic diseases common in Singapore. Participants will be invited to a follow-up visit every 3 to 5 years. Consent will be obtained at each follow-up visit. We will also ask for your consent to contact and invite you to participate in future public health-related research.

## **6. What is the approximate number of participants involved?**

We aim to follow-up on 35,000 participants of the SPHS.

## **7. What will be done if I take part in this research study?**

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

### Interview

7.2 First, an interview about your recent health will be conducted. The interview may include questions about your medical history, medications, physical activity, sleep quality, use of tobacco and alcohol, quality of life, and/or diet. If you are 65 years old or older, you may also be interviewed about your activities of daily living and physical functioning.

7.3 You may complete this interview by one of 3 possible ways:

- 1) self-completing an online survey (about 40min);
- 2) be interviewed face-to-face at your home or your preferred location (about 1.5hr long); or
- 3) be interviewed by phone (about 20min).

You can access the online survey via the URL in the study participation invitation letter that was mailed to you within 30 days of the letter. If you were not able to do so, a trained interviewer appointed by NUS will contact you to arrange a face-to-face interview. If the interviewer is not able to reach you, we will try to contact you by phone and conduct the interview over the phone. You may also contact us at 64789608 or sphs@nus.edu.sg to indicate if you wish to participate and your choice of interview method.

7.4 It is alright to skip any question you do not want to answer. The face-to-face interview will be audio-recorded for quality control and training purposes, and the audio file will be stored for at least 2 years. We may contact you later to verify certain information collected for this study.

### Research health screening

7.5 This study includes an optional health screening component which you can decide whether to participate after you have completed the interview. The interviewer can arrange an appointment for you to attend the health screening at NUS (Tahir Foundation Building/MD1, 12 Science Drive 2, S117549) or Bras Basah Complex (231 Bain Street, S180231). The health screening will take about 1.5-2hr.

7.6 The following procedures will be performed:

- 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 the functional status of the nerves supplying your feet;
- 5) Obtain a blood sample from your arm
  - (i) up to 9mls (or about 1 tablespoon) for creatinine, glucose and cholesterol tests to be performed by our research laboratory in SSHSPH
  - (ii) up to 20mls (or 2 tablespoons) to be stored for future Public Health Research\*
- 6) Obtain a urine sample to
  - (i) Test the protein level (this requires about 20mls of urine)
  - (ii) Store up to 6mls (about half a tablespoon) for future Public Health Research\*

- 7) 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.

*\*See Section 17 on future Public Health Research.*

7.7 You may also be selected for one or more of the following procedures:

- 1) Eyesight test;
- 2) Assess your walking and balancing;
- 3) Assess your lung function; and/or
- 4) Complete a survey about your well-being.

7.8 If you consent to donate a blood sample, we would prefer that you fast from 10pm 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 conditions or medication, please consult your doctor before fasting. If you chose not to fast, do inform the registration desk on your screening day.

7.9 Within 4 weeks of the health screening, you will be provided with a report of the results of your health screening. The results may include:

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

The report will also highlight to you any abnormal results from the tests performed. The tests are conducted for the purpose of research and they are not conclusive in determining medical risk factors or conditions. You should feel free to discuss these results with your own doctor.

Records linkage

7.10 Data from this research will be linked with additional data from your medical records or national registries to fulfil the research aims of this study.

**8 What are the proposed area(s) of research approved by the Institutional Review Board (IRB), where the IRB has waived the requirement that the removal of my tissue(s) be for therapeutic or diagnostic purpose?**

There is none in this study.

**9 Will there be reimbursement for participation?**

You will be reimbursed the following amounts:

|                                      |   |
|--------------------------------------|---|
| Upon completing the interview/survey | <ul style="list-style-type: none"> <li>• SGD\$15 in cash for face-to-face interview, <b>or</b></li> <li>• \$10 (NTUC vouchers/PayNow) for online survey, <b>or</b></li> <li>• \$5 (NTUC vouchers/PayNow) for phone interview</li> </ul> |
| Upon completing the health screening | SGD\$50 in cash   |

**10 Do I have to incur any expenses if I participate in this research?**

You will not incur any expenses for any tests or procedures conducted in this study.

**11 What are the possible risks, discomforts or inconveniences to me if I participate in this research?**

We will require you to answer the interview questions as accurately as possible. You can refuse to answer any questions that you are uncomfortable with by informing the interviewer.

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. Appropriate first aid will be administered should any injury occur.

Please inform the health screener if you have any pre-existing disease or are healing from injury so that the health screener will be able to assess if you may proceed with each component of the screening. This will not affect the reimbursement for your participation.

In addition, if you do not feel comfortable during the interview and/or the health screening, please inform the interviewer or health screener immediately so that we may assist you.

## **12 What benefits can I expect from participating in the research?**

There is no direct benefit to you by participating in this study. The knowledge gained may benefit the public in the future. Observational studies on chronic disease development take many years to produce results. We will publish any significant study findings to share with the public, researchers and policy makers.

Donation of samples is voluntary. If you choose to donate any samples, you also agree to the renunciation of your right to the samples and any intellectual property rights that may be derived from the use of the samples.

## **13 Are there any alternative procedures or treatments available to me? What are the potential benefits and risks of such alternatives?**

This is an observational study. There is no treatment involved in this study.

## **14 If I am injured as a result of participating in this research, what are the compensation and treatments available to me?**

If you follow the directions of the PI in charge of this study and you are physically injured, the NUS will pay the medical expenses for the treatment of that injury. By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

## **15 How will my privacy and the confidentiality of my research records be protected?**

All research data collected will be kept in accordance to the NUS' Research Data Management Policy. Research data (without personal identifiers such as name, NRIC number and contact information) used in any publication will be kept for a minimum of 10 years before being discarded.

Where any personal data is collected from you, we will keep the information confidential in accordance with the Human Biomedical Research Act and other applicable legal rules.

If you consent to donate your blood and/or urine, the samples obtained from you will be de-identified and stored at SSHSPH's tissue repository indefinitely upon the completion of this study. Stored samples may be used in future Public Health Research, subject to an IRB's approval.

We will not enter any research results into your health records. Therefore, your health insurance will not be affected in any way by your participation in this study.

For the purpose of conducting the operations of this research study, only the SPHS operations team, SSHSPH IT unit and authorised third parties will have access to your personal data and this will not be released to any other person, including the PI, co-investigators and members of the study team. To protect your confidentiality when analysing data, your research data will be de-identified and coded (i.e. personal identifying information will be replaced with a code number). All personal data (name, NRIC number and contact information) will be kept separate from the research data. The link between your personal data and the code number will be kept confidential by the SPHS operations team and SSHSPH IT unit. Only the SPHS operations team and SSHSPH IT unit are authorised to identify you via your name,

NRIC number and contact information to retrieve the test results and mail the health screening results to you.

**16 Will my participation in this research involve the use of any information that will identify me?**

The SPHS operations team will need your identifying information in order to conduct future follow-ups. Follow-ups will be done in 2 ways:

- 1) Surveying you in person about your lifestyle (diet, sleep, physical activity, smoking and drinking), personal and family medical history, well-being etc. and assessing your health through a repeat screening.

We plan to conduct this every 3 to 5 years. One of our biggest challenges in research like this one is following up on our participants who have changed their addresses. We may apply to the relevant ministry to request your most up-to-date address for us to contact you.

- 2) Extracting relevant medical record details such as the stage of disease or health condition, frequency of hospital visits and type of medical treatment etc.

It is not practicable for us to follow-up with you in person constantly and you may not be able to recall all of your health information. Certain information from your health records is helpful for researchers to study how diseases become worse, evaluate the cost effectiveness of different treatments and predict the economic burden of diseases to the individual and the country. Such information exists in your health records with health care institutions or in our national registries or national health information databases. Your name and NRIC number will be needed for the collection of medical status information from your records. Only information relevant to the purpose of this study and public health research in Singapore will be collected. Only the SPHS operations team and SSHSPH IT unit will collect the data, de-identify and code it (i.e. replace personal identifying information with code numbers) before storing the data in the SSHSPH research database. Researchers will have to apply for Institutional Review Board's (IRB) approval if they would like to use the de-identified and coded data for their research.

**17 Will any identifiable information obtained from me be used for future biomedical research?**

If you consent to take part in this study, your name, NRIC number and contact information will be retained so that we can invite you for a follow-up in this study in 3-5 years' time. The research data obtained from you at each visit will be linked to enable us to study how lifestyle changes affect health in each individual. The research data will be de-identified and coded before it is used in analyses.

If you consent, we may reach out to you to inform you of news about our research studies or invite you to take part in other Public Health Research.

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").

**18 What will happen to the samples taken from me upon completion of the research?**

If you consent, the samples obtained from you will be stored at the SSHSPH tissue repository for use in future Public Health Research. Blood and urine contain markers that tell us about certain conditions of the body, e.g. cholesterol and glucose levels. Blood can also be a source of DNA (the genetic material that distinguishes different people from one another) for the study of genes. Therefore, such samples are useful for studying the biological and genetic factors that may explain health statuses and the differences amongst individuals. If you agree only to provide samples for this study but not future research, we will only collect the amount required for this study and discard any remaining samples at the end of this study.

Your donated samples may contribute to research discoveries that enable commercial companies or institutions to develop new treatments or diagnostic tests. 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.

**19 Will the identifiable information obtained from me in the course of tissue donation be used for future research?**

If you consent to donate samples for future Public Health Research, your samples will only be provided for research in the de-identified and coded form. These research studies will be subject to an IRB's approval. Your samples will be used together with samples from many other participants from Singapore and/or other countries in Public Health Research studies.

**20 Will my blood be used in restricted human biomedical research?**

Your samples will not be used in restricted human biomedical research or research involving human-animal combinations.

**21 Will my tissue(s) be exported overseas or removed from Singapore?**

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 processing, storage, packaging and delivery of the samples, but NUS will not sell your samples to anyone for profit.

**22 Will I be re-identified in the event of incidental finding(s) arising during the biomedical research?**

It is possible that during the study we may find you have pre-existing medical issues that are unrelated to our study ("incidental finding"), but it is important that you seek medical advice. If that happens and you have consented to be contacted for this purpose, we will attempt to contact you. In the event that you have indicated not to be re-identified and notified, but NUS has determined that the incidental finding is of clinical significance, you may still be contacted to decide if you wish to be notified of the incidental finding at that time.

However, NUS will not cover the costs of medical consultations and any ensuing treatment. We will not share any information with your doctor without your consent.

**23 Under what circumstances will I be re-contacted for further consent?**

The SPHS operations team will contact you in the event of any new information that may be relevant to your willingness to continue in this study.

**24 Can I withdraw my consent to the research at any time?**

You can withdraw from the study at any time without giving any reasons, by informing the SPHS operations team verbally or in writing. Please note that the withdrawal of consent does not affect the research information obtained before the consent is withdrawn and such information may still be retained and used for research. If you had donated samples, we can discard only the unused portions of the samples that can be traced back to you. There will be no penalties or damages imposed on you should you withdraw your consent to participate in this study.