PARTICIPANT INFORMATION SHEET

For Interview and Screening

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) – Multi-Ethnic Cohort Phase 3 (MEC3)".

2. Principal Investigator and co-investigator(s)

Principal Investigator (PI): Professor Rob Martinus van Dam[1]
Co-investigator: Dr Sim Xueling[1]

[1] Saw Swee Hock School of Public Health (SSHSPH), National University of Singapore (NUS), Tahir Foundation Building, 12 Science Drive 2, #10-01, Singapore 117549 | Tel: 6516 4988

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

Please contact the SPHS operations team at **6478 9608** [Mondays to Fridays from 8.30am to 5.30pm, except public holidays] or email 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 (Attn: Dr Chan Tuck Wai, 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 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 Multi-Ethnic Cohort study is to follow-up on each participant every 3 to 5 years to find out about how lifestyle factors like diet, exercise and smoking, with and without the influence from genes and environment, can affect the development of common chronic diseases in Singapore. This will help us understand how we can change these factors and how changing these factors can prevent the disease or keep it from getting worse. This is a long-term study as the common chronic diseases such as heart disease, cancer and diabetes may take a long time to develop.

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) Aged 21 or older;
2) Singapore Citizen or Permanent Resident; and
3) Belong to Chinese, Malay or Indian ethnic group.

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 are not willing to provide such access to their medical or health records for research as certain data in the medical or health records of each participant will be required for this study.
4) Those who have a severe mental condition and are thus unable to give consent independently.
5) Those who have a history or current condition of stroke, heart attack, kidney failure or cancer.
6) Those who have had a vascular bypass surgery or angioplasty procedure (either stent or balloon) done.

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 recruit 30,000 participants to this study.

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, a trained interviewer appointed by NUS will contact you to arrange a face-to-face interview about your socio-demographic background, medical history, medications, diet, physical activity, sleep quality, use of tobacco and alcohol, quality of life, mental health and well-being. If you are 65 years old or older, you will also be interviewed about your activities of daily living and physical functioning.

7.3 The interview will take about 1-1.5hr 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. We may contact you later to verify certain information collected for this study.

7.4 You may also be selected for a sub-study on comparing 2 ways of conducting a nutrition survey. If you agree, you will be interviewed face-to-face on another version of the Online Nutrition Survey in addition to the one that you will self-complete or has already self-completed. The second survey must be completed 1 week later but not more than 3 weeks later. The face-to-face interview of the nutrition survey will take about 45min.

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 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) 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*
5) 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*

6) 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; and/or
7) Test your eyesight and take a photo of your retina (back of your eyeball); and/or
8) Assess your walking and balancing.

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

7.6 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.

7.7 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

7.8 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 for your time and effort, SGD$15 upon the completion of all surveys or interviews and SGD$50 upon completing the health screening.

You will receive an additional $10 as token of appreciation if you participate in the sub-study in which you completed a second nutrition survey.

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 (e.g. providers of financial, mailing, messaging, telecommunications, IT services etc.) will have access to your personal data and this will not be released to the 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 the National Electronic Health Records, with health care institutions or in our national registries. 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 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 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.