PARTICIPANT INFORMATION SHEET

Study title: Singapore Consortium of Cohort Studies (SCCS)-Diabetic Cohort (DC): A Pilot Follow-up with a Focus on Dietary Intake
Principal investigator: Prof Chia Kee Seng, National University of Singapore
SCCS-DC hot line: 6478 9608

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 purpose of our research is to learn more about how factors like diet and environment are important for diabetes management in Singapore.

Who can take part in this research?
Participants of the Singapore Consortium of Cohort Studies (SCCS)-Diabetic Cohort (DC) and who fulfill the below criteria will be invited to take part in this study:
1) Singaporeans and permanent residents of Singapore;
2) between age 45-64;
3) of Chinese, Malay and Indian ethnic groups; and
4) with established diagnosis of type 2 diabetes of more than 2 years on diet treatment or oral or insulin therapy

Due to the nature of this study, persons with the following medical conditions are not suitable to participate:
1) Pregnancy;
2) Mental illness;
3) Type 1 diabetes, MODY (Maturity Onset Diabetes of the Young) or secondary diabetes, e.g. diabetes secondary to chronic pancreatitis;

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

- **Interview**
Initially, trained interviewers will contact you and visit you in your home or at a place which is convenient to you. During this time, they will ask you to fill out a survey about your health, diet, and exercise, and your 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 recruitment and re-contact. The interviews will be administered at 2 separate time points within 2 weeks and each session will take approximately 1 hr. The information will be entered into a database. Certain clinical information such as year of birth, gender, ethnicity, ethnicity of parents, status, diagnosis, family history etc will be transferred to the Singapore Bio-Bank (SBB); no personal information will be kept at SBB. You will then be asked to attend a basic health screening on a separate day.

- **Basic Health screening**
The health screening will take approximately 1.5 hour. Our research staff will confirm an appointment with you. You will be asked to fast (no food or drinks, except plain water) from 10 pm the night before (or for 10-12hr prior to the health screening). You will also be asked to stop your medication for diabetes on the morning of your appointment and take it only after your blood sample has been collected. If you have other medical conditions (or/and on any medication), please consult the doctor before fasting. During the health screening, nurses and research assistants will:
1) measure your weight, height, waist and hip circumferences, and blood pressure;
2) measure the blood pressure at your ankle and arm;
3) use an instrument to determine the functional status of the nerves supplying your feet.
4) obtain samples of blood and urine for future studies and genetic research;
5) obtain blood sample for sugar, cholesterol and creatinine tests, and urine for protein level measurement; and
6) use an instrument to study the rhythm of your heart. You will be asked to undress to the waist and sticky pads called electrodes will be stuck to your chest, arms and legs.

You may be asked to provide a 24 hour urine sample. If you agree, you will be given a container to collect your urine over a 24 hr period.

- **Re-contact**
  You may be contacted later to obtain additional health information or to clarify uncertainties regarding the information collected. It is also possible that researchers may contact you again in 3-5 years to reassess your health status. Even if you have participated in this study, you may refuse to participate in later studies.

- **Record linkage**
  We will also ask for your consent to allow us to check on your health status by contacting your doctor or the National Registry of Diseases Office, or your medical records, 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?**
Researchers at the National University Hospital (NUH), National University of Singapore (NUS) and other healthcare/ research institutions are trying to learn more about diseases. 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 25 mls (about 5 teaspoons) of blood from a vein in your arm and/or collect up to 2 urine samples. Your samples (about 10 mls of blood and up to 12 mls of urine) will be stored at SBB. SBB is funded by A*STAR and serves as a national biobank facility. SBB works in close partnership with Singapore’s key medical and research institutions to collect, process, archive and distribute high quality biological samples in support of research needs. Samples are collected under strict ethical processes with informed consent and confidentiality. Strict security measures are in place to protect these invaluable samples that are Singapore’s national resources.

In addition, your samples will be stored for future research. 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 samples such as preparation, packaging and shipping, your samples will not be sold to anyone for our financial gain or commercial profit.
Appendix C

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.

As the research results will not be entered into your medical records, your health insurance will not be affected in any way.

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 be reimbursed for your time and effort in the following ways:

<table>
<thead>
<tr>
<th>Procedures completed</th>
<th>Reimbursement amount per person</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interviews</td>
<td>$30</td>
</tr>
<tr>
<td>Health screening</td>
<td>$50</td>
</tr>
<tr>
<td>24hr urine collection</td>
<td>$20</td>
</tr>
<tr>
<td>24hr urine collection (separate clinic visit)</td>
<td>$30</td>
</tr>
</tbody>
</table>

This paragraph does not waive any of your legal rights.

Will I find out results of the research?
Following the health screening, you will be provided with a copy of the results of your blood sugar, blood cholesterol, blood calcium, blood pressure, urine protein level and body mass index. 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.

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 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 that forms part of your medical record may be required for interpreting research results. With your permission, only SCCS staff will have access to these medical records to obtain the relevant data. Examples of such data include your age, gender, past health history, details of your present illness and family history of illnesses. Such information will be stored in SCCS and SBB 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. Instead, these will be replaced by code numbers for research and storage. 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 official ethics committee or IRB that oversees the ethical aspects of the research.

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 pamphlet, 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’.

There are 2 consent forms for the research. Consent Form A documents your consent to provide health data for research. Consent Form B documents your consent with regards to your biological samples and health screening results.

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. 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 Centre for Molecular Epidemiology at NUS. The principal investigator (person in charge of this research) is Prof Chia Kee Seng.

If you have any questions about:
1) this research — call the DC hotline at 64789608; or
2) SBB — call + (65) 64788489; or
3) 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 65161234.
CONSENT FORM A

Study title: Singapore Consortium of Cohort Studies (SCCS)-Diabetic Cohort (DC):
A Pilot Follow-up with a Focus on Dietary Intake
Principal investigator: Prof Chia Kee Seng, National University of Singapore
SCCS hot line: 64789608

I agree to provide my NRIC number for the use of this research. Yes ☐ No ☐

I agree to participate in the survey about my health, diet and exercise, and my use of tobacco, alcohol, and medicines. Yes ☐ No ☐

I agree to allow researchers to confirm my health status by contacting my doctor. Yes ☐ No ☐

I agree to allow researchers to confirm my health status by contacting the National Registry of Diseases Office. Yes ☐ No ☐

I agree to allow my relevant medical information to be gathered from my medical records for this study. Yes ☐ No ☐

I agree to allow my relevant medical information to be gathered from my medical records for future research. 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 is my choice and that refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled. In addition, I know that 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/or 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.

I have been informed that any questions pertaining to this research can be directed to SCCS 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).

If I have any questions about the Singapore Bio-Bank, please call +(65) 6478 8489.
Appendix D

* 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)

Day Month Year

Signature/ thumb print (participant)

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

Day Month Year

Signature/ thumb print (consent taker)

Name (as per NRIC) of translator

Relationship to participant

Day Month Year

Signature/ thumb print (translator)

* Include this section if participant is unable to understand English and read any of the translated consent documents available.

Ver 2 dated 31 August 10
CONSENT FORM B

Study title: Singapore Consortium of Cohort Studies (SCCS)-Diabetic Cohort (DC): A Pilot Follow-up with a Focus on Dietary Intake
Principal investigator: Prof Chia Kee Seng, National University of Singapore
SCCS hot line: 64789608

I agree to provide my NRIC number for the use of this research. [ ] Yes [ ] No

I agree to undergo a health screening which involves taking of up to 15mls (~3 teaspoons) of blood and a urine sample. [ ] Yes [ ] No

I agree to donate up to 10mls (~ 2 teaspoons) of my blood for future studies of diseases and health conditions. [ ] Yes [ ] No

I agree to donate a urine sample for future studies of diseases and health conditions. [ ] Yes [ ] No

I agree to donate my samples for future genetic research. [ ] Yes [ ] No

This material may be made available to qualified scientists, who will have to obtain approval from a relevant institutional review board.

I agree to allow my stored samples to be used for commercial development. [ ] Yes [ ] No

I agree to be re-contacted in 3-5 years time. [ ] 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 is my choice and that refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled. In addition, I know that 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/or 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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Name (as per NRIC) of participant

NRIC (participant)

Day  Month  Year

Signature/thumb print (participant)

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

Day  Month  Year

Signature/thumb print (consent taker)

Name (as per NRIC) of translator

Relationship to participant

Day  Month  Year

Signature/thumb print (translator)

* Include this section if participant is unable to understand English and read any of the translated consent documents available.