# PARTICIPANT INFORMATION SHEET AND CONSENT FORM

You are being invited to participate in a research study. Your participation in this study is entirely voluntary. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Your questions will be answered clearly and to your satisfaction. Please read the information provided here carefully. If you agree to participate, please sign the consent form. You will be given a copy of this document.

## STUDY INFORMATION

**Study Title: A pilot study to evaluate Equol and its effects on menopausal symptoms experienced by women in Singapore**

This research study is recruiting at the following SingHealth institution(s). Please note that the word "SingHealth" refers to the institution where you are recruited into the study.

**KK Women's and Children's Hospital**
Principal Investigator:
Dr Ang Seng Bin
Family Medicine Service
Tel: 63941102
Institution Mainline: +65 62255 554

## PURPOSE OF THE RESEARCH STUDY

The purpose of this research study is to measure the urine equol (equol is a compound which is converted from soy in our diet) concentration in women. Soy-based diet is converted to equol by the gut bacteria in some women. Equol has been shown to have some Oestrogen-like effect and studies have shown that in women who have been shown to be able to produce equol from soy-based diet, they experienced milder menopausal symptoms compared to those who cannot produce equol. This study will evaluate the prevalence of equol producers and non-producers and their prevalence of menopausal symptoms.

You were selected as a possible participant in this research study because you are between 40 and 60 years of age.

This research study targets to recruit 300 participants from KK Women's and Children's Hospital.

## STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY

You will be required to:

Attend the screening and enrolment. Basic demographic information will be obtained. Your height, weight and blood pressure would be measured. You would have to answer several questionnaires regarding menopausal symptoms, dietary intake of soy products, activity and bodily pain. This is estimated to take 30 minutes.

Upon confirmation of your eligibility for the study, we will provide you with containers to collect urine as well as a soy-based protein bar for you to bring home. The following are the processes that you will undertake as part of the study.

Day 1:

- To collect the first morning urine of between 5ml-10ml in the containers provided. You will be required to seal the containers in the bags provided. Keep the container in room temperature in a cool environment till day 2 urine sample is collected.
- In the evening, consume a soy-based protein bar.

Day 2:

- To collect the first morning urine of between 5ml-10ml in the containers provided. You will be required to seal the containers in the bags provided. Following that, call the courier to despatch the day1 and day 2 urine samples to KK Women's and Children's Hospital.

The study involves the following:

**Questionnaire:**
We will ask you to complete questionnaires about menopausal symptoms, food intake, bodily pain and function and vaginal symptoms. This will take around 30 minutes.

**Biological materials:**
We will collect the following samples ("biological materials"):
We will require you to self-collect 2 samples of first morning urine of between 5 to 10 mls each over 2 days. The de-identified samples will be stored in KK Women's and Children's Hospital and sent in batches to a laboratory in Japan for further analysis of the equol concentration. It will not be used in research involving human-animal combinations, which is restricted by Singapore law.

*Your participation in the study will last 3 days. You will need to visit KK Women's and Children's Hospital once in the course of the study.*

*If you agree to participate in this study, you should follow the advice and directions given to you by the study team.*

## WHAT IS NOT STANDARD CARE OR IS EXPERIMENTAL IN THIS STUDY

The study is being conducted because the prevalence of equol producers in Singaporean women has not been established. We hope that your participation will help us to determine whether women who are able to produce equol from dietary soy-based diet have milder menopausal symptoms compared to those who are unable to produce equol. Completion of questionnaires and collection of urine samples are being performed for the purpose of the research.

## POSSIBLE RISKS, DISCOMFORTS OR INCONVENIENCES

**Collection of urine samples:**
Collection of urine may cause inconveniences.

**Questionnaires/ surveys/ interviews:**
*Some of the questions might make you feel uncomfortable or upset. You may refuse to answer any of the questions and/or take a break at any time during the study.*

**Personal privacy and confidentiality:**
*This study uses information that may affect your privacy. To protect your confidentiality, only a unique code will be used to identify data and/or biological material that we collected from you.*

*As there will be a link between the code and your identifiable information, there is still a possibility of data breach. A data breach is when someone sees or uses data without permission. If there is a data breach, someone could see or use the data we have about you. Even without your name, there is a chance someone could figure out who you are. They could misuse your data. We believe the chance of this is very small, but it is not zero.*

## POTENTIAL BENEFITS

There is no benefit from participation in this study. However, your participation in this study may add to the medical knowledge about the prevalence of equol producers in Singaporean women and its effect on menopausal symptoms.

## ALTERNATIVE IF YOU DO NOT PARTICIPATE IN THE STUDY

*There is no alternative to the study procedures. You can choose not to take part in this study. The study procedures will not be carried out.*

## COSTS & PAYMENTS IF PARTICIPATING IN THIS STUDY

There is no cost to you for participating in this research study. *The cost of your usual medical care (procedures, medications and doctor visits) will continue to be billed to you.*

*If you take part in this study, the following will be performed at no charge to you: Urine analysis, courier services for despatching urine samples to KK Women's and Children's Hospital, soy-based protein bar. These costs will be borne Otsuka Pharmaceuticals (Singapore) Pte. Ltd., which is the sponsor of the study.*

*You will be reimbursed $50, for transport, time, and inconvenience after completion of the screening visit and collection of 2 samples of urine.*

*There will not be reimbursement for partial completion of the study.*

## INCIDENTAL FINDINGS

There will not be any incidental findings arising in this research. "Incidental findings" are findings that have potential health or reproductive importance to research participants like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study.

## WHAT HAPPENS TO THE SAMPLES COLLECTED FOR THE RESEARCH

The biological materials collected for this research study will be deemed to be donated to Otsuka Pharmaceuticals (Singapore) Pte. Ltd. as a gift. By agreeing to this, you give up your rights to the biological materials. If the use of your biological materials and/or your data results in intellectual property rights and commercial benefits, you will not receive any financial benefits or proprietary interest.

The biological materials will be used only for the purpose of this research and will be discarded or destroyed upon completion of the research study.

## PARTICIPANT'S RIGHTS

Your participation in this study is entirely voluntary. You have a right to ask questions, which the study team will do their best to answer clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (or your legal representative, if relevant) will be informed in a timely manner by the Principal Investigator or his/her representative and will be contacted for further consent if required.

## WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation in the study at any time, without giving any reasons and without your medical care being affected. If you decide to stop taking part in this study, you should tell the Principal Investigator.

*Any remaining biological materials that have been collected for the study will be destroyed following the withdrawal of your consent if they are individually-identifiable and (i) have not*

*been used for research; OR (ii) have been used for research but it is practicable to discontinue further use of the samples for the research.*

However, any research information or data obtained before your withdrawal of consent will be retained and may continue to be used. This is to allow a complete and comprehensive evaluation of the research study.

Your study doctor, the Principal Investigator of this study may stop your participation in the study at any time for one or more of the following reasons:

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- The Principal Investigator decides that continuing your participation could be harmful to your health or safety.
- Pregnancy
- You require treatment not allowed in the study.
- The study is cancelled.

## RESEARCH RELATED INJURY AND COMPENSATION

**I**f you follow the directions of the Principal Investigator of this research study and you are injured due to the research procedure given under the plan for the research study, our institution will provide you with the appropriate medical treatment.

Payment for management of the normally expected consequences of your treatment (i.e. consequences of your treatment which are not caused by your participation in the research study) will not be provided.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence.

## CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Your participation in this study will involve the collection of Personal Data. “Personal Data” means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. Examples of personal data include name, national registration identity card (NRIC), nationality, passport information, date of birth, and telephone number.

Personal Data collected for this study will be kept confidential and stored in Singapore. Your study records and medical records (if applicable), to the extent required by the applicable laws and regulations, will not be made publicly available. To protect your identity, your Personal Data will be labelled with a unique code. The code will be used in place of your name and other information that directly and easily identifies you. The study team will keep a separate file that links your code to your Personal Data. This will be kept in a safe place with restricted access. In the event of any data sharing with third parties (e.g. funding agencies, research collaborators) whether locally or overseas and publication regarding this study, your identity will remain confidential.

However, the monitor(s), the auditor(s), the Institutional Review Board, and the regulatory authority(ies) will be granted direct access to your original medical records (if applicable) and

study records to verify study procedures and data, without making any of your information public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by Singhealth, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties as mentioned above. To the fullest extent permitted by applicable law, under no circumstances will Singhealth and/or its affiliates be liable for any direct, indirect, incidental, special or consequential loss or damages arising out of any data breach event.

All *data collected in this study are the property of Otsuka Pharmaceuticals (Singapore) Pte. Ltd. The data will be used for the purpose of this research study only.*

By participating in this research study, you are confirming that you have read, understood and consent to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

## WHO HAS REVIEWED THE STUDY

This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

If you have questions about your rights as a participant, you can call the SingHealth Centralised Institutional Review Board at 8126 3660 during office hours (8:30 am to 5:30pm).

## WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

If you have questions about this research study or in the case of any injuries during the course of this study, you may contact your study doctor, the Principal Investigator listed under STUDY INFORMATION section, at the beginning of this document.

If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

# CONSENT FORM FOR RESEARCH STUDY

**Study Title:**
A pilot study to evaluate Equol and its effects on menopausal symptoms experienced by women in Singapore

## Declaration by Research Participant

- I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

- I understand the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to discuss and ask questions about this study and am satisfied with the information provided to me.

- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons.

- By participating in this research study, I confirm that I have read, understood and consent to the Singhealth Data Protection Policy.

| _____ | _____ | _____ |
|---|---|---|
| Name of participant | Signature/Thumbprint (Right / Left) | Date of signing |

## To be completed by translator, if required

The study has been explained to the participant/ legal representative in

_____ by _____.
Language Name of translator

## To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this informed consent form had the study fully explained to him/her in a language understood by him/ her and clearly understands the nature, risks and benefits of the participant's participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative giving the consent.
- I have taken reasonable steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Witnessed by: _____ _____

Name of witness Date of signing

_____

Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant's or legal representative's thumbprint). After the written consent form and any written information to be provided to participant is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under the HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

## Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this consent form had the study fully explained to him/her and clearly understands the nature, risks and benefits of the participant's participation in the study.

| _____ | _____ | _____ |
|---|---|---|
| Name of Investigator/ Person obtaining consent | Signature | Date |