# PARTICIPANT INFORMATION SHEET AND CONSENT FORM

**Consent Form Version:** Version 2.0
**Consent Form Date:** 23/09/2022

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 will be explained to you and you will be given the chance to ask questions. Your questions will be answered clearly and to your satisfaction.

Please read the information provided here carefully and ask questions about anything you don't understand before deciding whether or not to take part.

After you are properly satisfied that you understand this study, and that you wish to take part in the study, you must e-sign this informed consent form. You will be given a softcopy of the signed consent form.

## 1. STUDY INFORMATION

**Protocol Title:**

**A decentralized study on dietary influences on the cognitive function**

**Principal Investigator's Contact Details**

Prof Jeroen Schmitt PhD, Senior Principal Investigator,
Singapore Institute of Clinical Sciences (SICS), A*STAR
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Phone: 6407 4060
Email: bh2research@sics.a-star.edu.sg

## 2. PURPOSE OF THE RESEARCH STUDY

The purpose of the study is to understand the influence of changes in blood glucose levels after meal and snack consumption on cognition and mood in a real life setting over a 6-day period.

You are selected as a possible participant in the study as you meet all the following criteria:

- Aged 50 - 65 years
- Own and use a smartphone and are capable to run the study applications (Android 4.4 or later, OS 12.0 or later)
- Have adequate fluency in the English language
- Have sufficient vision and hearing to complete study procedures
- Are willing and able to participate and to give written consent to comply with study procedures

Persons who meet one or more of the following criteria will not be eligible to participate in the study:

- Presence or history of a metabolic, neurological, or psychiatric illness
- Use of prescription or over the counter medication that may influence gastrointestinal, metabolic, or neurological functioning
- Known food allergies
- Use of illicit drugs
- Alcohol intake >1 units/day
- BMI <18.5 or >30 kg/m² (based on weight and height)
- Are a member of the research team or their immediate family members. Immediate family member is defined as spouse, parent, child, or sibling, whether biological or legally adopted

The study will recruit at least 24-40 subjects (male & female) from the community over a period of 6 months.

## 3. STUDY PROCEDURES

This study is a 'decentralized study', meaning that all study procedures, measurements, and interventions will be conducted while you live your usual life, without the need to visit the research facilities. This will allow us to establish the impact of dietary glucose fluctuations in a real-life situation, rather than an artificial laboratory setting.

If you agree to take part in this study, you will be asked to undergo two treatment periods of three consecutive days, with a washout period of four days. The treatment periods will be on Tuesday, Wednesday, and Thursday in two consecutive weeks. Total study duration is 13 days (three preparation day, three test days, four washout days, three test days).

### Study Schedule & Procedures:

During the study period, you will be asked to consume study snack (either a low GI snack or normal snack) in the morning and in the afternoon on each day. The snack given will be identical throughout each study period (week 1 & week 2). The sequence of the snack to be consumed will be randomized. You will also have to eat the study meals (breakfast and lunch), complete the cognitive tasks on your mobile phone (6 times in a day) and continue to wear the glucose sensor till the study ends. At the end of the three test days i.e. on Friday you will be asked to fill a feedback form for your overall experience.

Delivery Day (Friday Day -3 to 0)

On Friday the week prior to the first test day, all the necessary materials (including study snacks) with detailed instructions for Z4IP app, dry blood spot kit, glucose sensor and meals will be delivered to your home/office.

Preparation Days (Saturday, Sunday, Monday; day -2 to 0)

During the weekend you will have to install the Z4IP app on your mobile phone and complete three practice tests at the latest by Monday. You will also be asked to provide a few drops (2-4 drops) of blood through a finger prick, using a special 'dry blood spot kit.

On Monday morning, you will have to place the glucose sensor on your non-dominant arm. Alternatively, a study representative will visit at your home/workplace at a mutually agreed time in the morning to assist with the placement and activation of the glucose sensor andto collect the dry blood spot kit.

On Monday of each testing week, study meals will be delivered at your home. Store them as per the given instructions. You will have to eat these study specific breakfasts, lunches, and snacks for three test days (Tuesday, Wednesday, and Thursday). You will be given a list of meal options to choose your preferred study meals.

Test days in week 1- Tuesday, Wednesday, Thursday (day 1 to 3) - Each test day will start at 7.30am and end at 6pm. On each test day you will have to eat study breakfast at 7:30am and eat the lunch provided (~12.00pm). Do the cognitive tests (Z4IP) on your mobile phone and answer short questions about your mood, sleep, appetite, dietary intake, health problems and use of medication. These tests will take around 5 mins and will happen at 8.00am, 9.50am, 11.50am, 1.00pm, 3.50pm and 17.50pm. You will have to consume assigned study snack twice per day (10.00am and 4.00pm). You will not be allowed to eat any other foods during the test days (until 6pm). You are free to consume any food items at dinner after 6pm or in the evening until 10pm. At the end of the three test days i.e. on Friday you will be asked to fill a feedback form for your overall experience.

Friday, Saturday, Sunday, and Monday (day 4 to 7) are the washout periods where you are not required to follow any study procedures such as eating study meals or doing cognitive tests. However, you will have to continue to wear glucose sensor on your arm throughout these days.

Test days in week 2- Tuesday, Wednesday, Thursday (day 8 to 10): You will be asked to do the same activities as on the previous test days of week 1. You will have to eat study breakfast at 7:30am and lunch (~12.00pm). Do cognitive tests and answer few questionnaires on the mobile application at 8.00am, 9.50am, 11.50am, 1.00pm, 3.50pm and 17.50pm. Eat assigned study snack twice per day (10.00am and 4.00pm). Fill the feedback form at the end of three test days.

After finishing all the test days, on the following day i.e., Friday (Day 11) you can remove the glucose sensor gently from your arm and return it to the study team. Please remember to keep the sensor inside the mailer kit and mail it back to SICS.

Please note throughout the study, you can live your habitual life and work as usual. However, it will be necessary to make small adaptations to your schedule to allow performing cognitive tests, having study meals and snack at the dedicated times. For example, you will be required to stop your work and move to a quiet place to do the cognitive tests and take the study meals and snacks with you if you leave your home. The use of alcohol during the or

on the evening before the test days (from 6 pm) or at any time during the test days is prohibited. The consumption of snacks or meals (breakfast, lunch) other than the products provided for study during the test days (until 6 pm) is not permitted.

Throughout the study you can always contact the study staff whenever you feel it is necessary or in doubt regarding the study procedures. The study staff will also send you reminders on your mobile phone to consume the meals, snacks and to do the tests at the scheduled times.

**Restricted Research**

The human biological materials collected will not be used in restricted human biomedical research involving human-animal combinations in accordance to the Human Biomedical Research Act 2015 of Singapore (HBRA).

**Storage, Supply, Use or Export of Human Biological Material and/or Health Information**

To protect your identity, privacy and confidentiality, your human biological materials and/or stored data will be labelled with a code instead of information that directly identifies you (e.g. your name, NRIC, date of birth, etc.). We will keep a separate file (key) that links your code to your individually-identifiable information. When we share your data and biological materials with other researchers, it will be in coded manner. They will not be able to identify you from the coded data and biological materials. The study data will be retained for a period of 10 years.

Biological samples (dry blood spot) will be analyzed for HbA1c levels only and destroyed after analyses. De-identified health data may be used and/or merged with other data sets for research purposes beyond the scope of this study for a maximum period of 10 years.

## 4. YOUR RESPONSIBILITIES IN THIS STUDY

If you agree to participate in this study, you should:

- follow the study procedures and instructions from the study team for the duration of the study
- be contactable by the study team during the conduct of the study
- inform the study team immediately if you are unsure about any study procedures, encounter any issues, or if any changes in your personal situation emerge that may impact your ability to participate in the study.

## 5. POSSIBLE RISKS, DISCOMFORTS OR INCONVENIENCES

- **Dry Blood Spot Sampling:** The dried Blood Spot sampling requires a self-administered finger prick, which may cause momentary discomfort and pain at the site of the needle stick. Rarely, a finger prick may cause fainting or infection. Instructions and tools to disinfect, clean and cover the area will be provided to you.

- **Continuous Glucose Monitoring:** The Continuous Glucose Monitoring Sensor is a minimally invasive device. This means that a small flexible sensor is inserted in the skin and underlying tissue by means of a micro-needle in the applicator. The application is generally painless, but in some cases the insertion may cause mild momentary pain and discomfort. In rare cases, swelling or skin irritation may occur due to an allergic reaction to the adhesive material. In rare cases, the sensor may cause an infection. If you experience any pain, discomfort or adverse reactions at anytime after administering the sensor, please contact the study staff. You may also choose to remove the sensor. In such an event, your participation in the study will be halted.

- **Personal privacy and confidentiality:** This study uses human biological material and health information. To protect your privacy, only a unique code number will be used to identify biological materials and/or health information that we collect from you.

  All data is stored in a secure and access-protected locations. Your code will be linked to your individually identifiable information in a separate data source that is stored separately from your health-related data. In the case of a data breach (meaning somebody accesses your data with permission), both sources have to be accessed to link your health data with your identity. Although this is unlikely, it is not impossible.

## 6. POTENTIAL BENEFITS

Your participation in this research does not directly benefit you personally. However, study results will help to understand the relation between blood glucose levels and cognition and mood. This may lead to better dietary guidelines and advice, as well as food products, that support cognitive functioning and mood.

## 7. COSTS & PAYMENTS FOR PARTICIPATING IN THIS STUDY

If you take part in this study, you will not be required to pay for any of the procedures and meals provided. You will be reimbursed for your time and inconvenience costs as follows:

- You will be reimbursed $20 each time you complete all the study procedures on a test day. Additionally, you will be reimbursed $80 bonus for completing the full study protocol. You will be reimbursed a total $200 completing the full study.
- If you do not complete the study for any reason, a prorated reimbursement will be given to you based on the number of completed test days.

## 8. INCIDENTAL FINDINGS

During the course of the study, there is a possibility that we might unintentionally become aware new information about your health condition. These are called “incidental findings”. These findings may include indications of (risk of) a disease, particularly a compromised glucose control, diabetes or metabolic syndrome, as measured by glycated haemoglobin (HbA1c) levels in your blood or patterns of glucose levels from the glucose sensor. Such findings may indicate a need for medical follow-up and may impact your health insurance.

You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you.

If you agree to be re-identified and notified, a member of the study staff will explain the incidental finding to you and discuss and advise you on the next steps to follow. You may wish to do more tests and seek medical advice to confirm this incidental finding. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. A referral letter will be given to you for follow-up with GP, where applicable.

## 9. PARTICIPANT'S RIGHTS

Your participation in this study is entirely voluntary. Your questions will be answered 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 will be informed in a timely manner by the Principal Investigator or study team and further consent may be required.

By signing and participating in the study, you do not waive any of your legal rights to revoke your consent and withdraw from the study at any time.

## 10. WITHDRAWAL FROM STUDY

Your decision to participate in this research is entirely voluntary. You are free to withdraw your consent and discontinue your participation at any time without prejudice to you. Please inform the study staff if you decide to stop taking part in this study.

If you withdraw from the study for any reason,

- You will receive a pro-rated payment for the completed test days ($20 SGD per day)
- As instructed by the study staff, you will discard and/or return all study materials (meals, sensors, kits)

However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

The biological samples collected for the study will be deemed to be given to SICS and will not be returned to you. You will also not have any right or claim to any share in the commercial gain derived from the research (if any). However, you retain your right to ask the Principal Investigator to discard or destroy any remaining samples if they have not been anonymised.

The Principal Investigator of this study may stop your participation in the study at any time due to 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
- You need treatment that is not allowed in the study
- Study is cancelled

## 11. RESEARCH RELATED INJURY AND COMPENSATION

If you follow the directions of the Principal Investigator/study team and are physically injured due to study procedure given under the plan for this study, SICS 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.

Payment for management of the normally expected consequences of your treatment will not be compensated.

SICS without legal commitment will compensate you for the physical injuries arising from your participation in the study without you having to prove SICS is at fault. There are however conditions and limitations to the extent of compensation provided.

## 12. 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. This includes medical conditions, medications, investigations and treatment history.

Information and “Personal Data” collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Only the study team will have access to your personal data. However, the Institutional Review Board, auditors and regulatory authorities will be granted direct access toyour original study and/or medical records to check study procedures and data, without making any of your information public.

Data collected and entered in the Case Report Forms are the property of SICS. In the event of any publication regarding this study, your identity will remain confidential.

Research arising in the future, based on your “Personal Data”, will be subject to review bythe relevant institutional review board.

SICS, A*STAR will take appropriate steps to ensure it complies with the data protection requirements in the Personal Data Protection Act while your Personal Data remains in its possession or under its control. Any publications or press releases arising from the study will not contain any personal identifying information.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by SICS, and (ii) the disclosure of such Personal Data to our authorised service providers (e.g., Courier and Delivery services) and relevant third parties.

By participating in this research study, you are confirming that you have read, understood and consent to the A*STAR Personal Data Protection Policy **(Annex A)**.

## 13. 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 study, you may contact the research staff:

**Principal Investigator**
Prof Jeroen Schmitt PhD, Senior Principal Investigator,
Singapore Institute of Clinical Sciences (SICS), A*STAR
30 Medical Drive, Level 6, Singapore 117609
Phone: 6407 4060
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## 14. CONSENT TO BE CONTACTED FOR FUTURE RESEARCH

You are being asked for permission to be contacted in the future for participation in research studies that you may be suitable for. If you agree to be contacted, your information and contact details will be entered and stored in a secured database in SICS. Your information and contact details will not be released to any parties outside SICS without your permission. When investigators from SICS identify you to be suitable for a particular research study, the investigators or authorised personnel from SICS will contact you to inform you about the research study. Your decision to be contacted for future research studies is completely voluntary and separate from your decision to participate in this study. Your decision will not affect your medical care or any benefits to which you are entitled. You may change your mind at any time by contacting bh2research@sics.a-star.edu.sg.

## 15. WHO HAS REVIEWED THE STUDY

This study has been reviewed by the A*STAR Institutional Review Board (IRB) for ethics approval.

If you have questions about your rights as a participant, you can contact the A*STAR IRB at hbro@hq.a-star.edu.sg

## Annex A

# A*STAR's Personal Data Protection Brief

The A*STAR Personal Data Protection Brief sets out how the A*STAR GROUP (including the Research Institutes, centres, networks, consortia, subsidiaries and other units) collect, use or disclose Personal Data in compliance to the PDPA.

- **Consent, Purpose and Notification**
  A*STAR GROUP/ENTITY will notify individuals of the purposes for which their Personal Data is collected, used or disclosed by the A*STAR GROUP/ ENTITY and ensure that the individuals' consent have been obtained for such purposes.

- **Access and Correction**
  Individuals can make a written request to gain access, correct their Personal Data or withdraw consent to the processing of their Personal Data.

- **Accuracy**
  A*STAR GROUP/ENTITY will take reasonable efforts to ensures that Personal Data collected by or on behalf of the A*STAR GROUP/ ENTITY is accurate and complete.

- **Protection**
  Reasonable security arrangements will be put in place to protect Personal Data in the A*STAR GROUP's/ENTITY's possession or control from unauthorised access, collection, use, disclosure, copying, modifying, disposal or such similar risks.

- **Retention**
  Personal Data will be retained for as long as it is necessary to fulfill the purpose for which it is collected or for business or legal purposes, or in accordance with applicable laws.

- **Transfer Limitation**
  A*STAR GROUP/ENTITY will put in place agreements to regulate third party service providers outside Singapore to process Personal Data from A*STAR GROUP/ENTITY for administrative, business and/or legal purposes.

Queries in relation to A*STAR Personal Data Protection practices should be directed to our DPO at dpo@a-star.edu.sg .

## CONSENT FORM FOR RESEARCH STUDY

### Details of Research Study

**Protocol Title:**
**A decentralized study on dietary influences on the cognitive function**

**Principal Investigator**
Prof Jeroen Schmitt PhD, Senior Principal Investigator,
Singapore Institute of Clinical Sciences (SICS), A*STAR
30 Medical Drive, Level 6, Singapore 117609
Phone: 6407 4060
Email: bh2research@sics.a-star.edu.sg

### Participant's Consent

I agree to participate in the research study as described and, on the terms, set out in theParticipant 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 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 and without my medical care being affected.

By participating in this research study, I confirm that I have read, understood and consent to the A*STAR Personal Data Protection Policy.

### Consent to be Re-identified and Notified in the case of an Incidental Finding

Please check one of these boxes:

☐ Yes, I agree to be re-identified and I want to be contacted in the case of an incidental finding from this current research.

Phone:

Email:

☐ In the event that I cannot be reached, please contact the following person nominated by me:

Name:

Phone:

Email:
☐ No, I do not agree to be re-identified and I do not want to be contacted in the case of an incidental finding from this current research.

**Consent for the Use of Human Biological Samples and/or Data for Future Research**

| **Please indicate your options by indicating a tick (√) on the checkboxes:** | **Yes** | **No** |
|---|---|---|
| Do you agree to donate your data for future research? If you do not agree, the data will not be used after the completion of this study.<br><br>**If you indicate "Yes" to the above options,** please choose one of the following options:<br>☐ There are no restrictions on the kind of research that may be done with my data.<br><br>☐ The investigator may use my data for future research for current and related/sub studies. | ☐ | ☐ |

**Consent to be contacted for Future Research**

☐ Yes, I agree to be for contacted for future research that I may be eligible for.I agree to be contacted via:

Phone_____

Email _____

☐ No, I do not agree to be contacted for future research.

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

**To be completed by parent / legal guardian / legal representative, where applicable.**

I hereby give consent for the above participant to participate in the proposed research study.

The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

I confirm that I have read, understood and consent to the A*STAR Personal Data Protection Policy.

| Name of participant's parent /legal guardian/ legal representative | Signature/Thumbprint (Right/Left) | Date of signing |
|---|---|---|

**To be completed by translator, if required.**
(If the participant is unable to understand English and read any of the translated consent documents available.)

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

_____ by _____.
Language Name of translator

**To be completed by witness, where applicable.**
**(only for interventional, invasive and/or restricted research under HBRA)**

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant 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 his / her participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant giving the consent.
- I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

| Name of Witness | Signature | Date of signing |
|---|---|---|

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 or legal representative 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 HBRA (refer to HBRA, Part 3, Section 6(d) and HBR Regulations 2017, Part 4 Section 25 and 26).
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 and clearly understands the nature, risks and benefits of his / her participation in the study.

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