

Appendix 1 – Participant Information Sheet

Project Title:	Development of a novel Asian Mediterranean Diet and its acceptability in Non-Alcoholic Fatty Liver Disease (NAFLD) – a pre-intervention study (“Research”)
SIT-IRB Application No.:	RECAS-0244
Principal Investigator’s (“PI”) Name and Contact Details:	Dr Verena Tan Singapore Institute of Technology Dover Drive verena.tan@singaporetech.edu.sg +65 65923461

Instructions to Participant

Please read this Participant Information Sheet carefully and ask any question that you may have about this Research. Your participation is entirely voluntary. Your decision to participate (or not) will not affect any current or future status or relationship with the Singapore Institute of Technology (“SIT”).

What is the investigational nature of this Research?

This research is a pre-intervention study to evaluate the acceptability of the newly developed Asian Mediterranean Diet among participants diagnosed with Non-Alcoholic Fatty Liver Disease (NAFLD). This Research is conducted over 2 phases. The first phase consisted of development of the novel Asian Mediterranean Diet. The current second phase that we are recruiting subjects for, is to evaluate the acceptability of the diet.

What is the purpose of this Research?

This study aims to investigate the acceptability of the novel Asian Mediterranean diet among participants diagnosed with NAFLD.

Why have I been invited to take part in this Research?

You have been invited to take part in this Research because you have been diagnosed with Non-Alcoholic Fatty Liver Disease by your physician. We would like to seek your views on the acceptability of the newly developed Asian Mediterranean diet.

How many participants will be involved in this Research?

There will be 30 participants involved in this research.

What will I be expected to perform if I agree to participate in this Research?

If you agree to be in this Research, you will be asked to do the following things:

- 1) Visit SIT@Dover for 2 study visits.
- 2) For each study visit, 7 food items will be served to you in appropriate tasting portions in the sensory laboratory.
- 3) You will be required to taste the food and provide your feedback on the appearance, aroma/taste, texture, and overall acceptability of the food served to you via a food tasting evaluation form (online or physical copy).

What are the foreseeable risks/discomforts/inconveniences arising from this Research?

There are minimal risks, discomfort and inconveniences foreseen from this Research. Food allergy is a potential risk that may arise from this food tasting. Kindly declare if you have any food allergy, intolerance or diet restrictions.

What are the expected benefits from participating in this Research?

There are no medical or health benefits from participating in this research. However, as this is a novel Asian Mediterranean Diet, you will be the first to savour the recipes developed.

What are the compensation and treatment available if I suffer from an injury due to my participation in this Research?

During your participation in this Research, please follow the directions of research in-charge of this Research at all times and remember to declare your food allergy, intolerance, and restrictions. If you feel any discomfort, please notify the PI immediately at verena.tan@singaporetech.edu.sg. In the event of injury arising from participation in this Research, compensation and treatment will be considered on a case-by-case basis. For more information regarding this Research and the rights of research participants, please contact SIT-IRB Secretariat by email: irb@singaporetech.edu.sg.

Will I incur any expense as a consequence of my participation in this Research?

There are no additional expenses for your participation in this research.

Will I receive any payment for my participation in this Research?

You will be reimbursed with grocery vouchers for their time and transport upon completion of 2 study visits.

Will the PI collect my personal data, health information or biological materials for this Research and how will the PI keep my personal data, health information or biological materials confidential?

Note: In accordance with SIT's Research Data Management Policy, ALL research data shall be held for 10 years after publication or after the completion of the project, whichever is later.

(1) Personal Data:

- a. SIT will collect your food habits for the past 1 year using a questionnaire. Anthropometric data (weight, height and body mass index, waist circumference) and body composition (using bioelectrical impedance) will be assessed once for the purpose of this Research.
- b. The PI will only disclose your personal data to members of his/her research team on a need-to-know basis if necessary.
- c. All personal data will be coded (i.e. only identified with a code number) at the earliest possible stage of the research.

(2) Health information:

- a. SIT will collect your information from our collaborators consisting of information such as liver enzymes (ALT, AST, Albumin, bilirubin, alkaline phosphatase and GGT), platelet count, lipid profile (total cholesterol, LDL, HDL, TG) and diagnosis for NAFLD for the purpose of this Research.
- b. The PI will only disclose your health information to members of the research team on a need-to-know basis if necessary.
- c. All individually-identifiable health information will be coded (i.e. only identified with a code number) at the earliest possible stage of this research.

(3) Biological materials:

SIT will not be collecting your biological materials for this Research.

(4) Whether your personal data, health information and/or biological materials will be disclosed in a publication or presentation?

We will not include any of your personal data, health information or biological materials in any publication or presentation.

(5) Records of this Research:

The records of this Research will be kept strictly confidential. All physical records will be kept in a locked file and all electronic information will be coded and secured through password encryption.

Will my personal data, health information and/or biological materials (as applicable) collected for this Research be used for future biomedical research?

No

Under what circumstances will I be contacted for further consent?

Not applicable

Will I be re-identified in the case of an incidental finding?

This Research does not provide for re-identification in case of an incidental finding.

Can I withdraw my consent to participate in this Research?

You may withdraw your consent to participate in this Research at any time. Please contact verena.tan@singaporetech.edu.sg if you wish to withdraw your consent.

However, please note that your withdrawal of consent does not affect the research information obtained before your consent is withdrawn and such information may be retained and used for this Research.

If I wish to obtain further information on this Research or provide feedback in relation to this Research, who should I contact?

To obtain further information on this Research or provide feedback in relation to this research, please contact the Principal Investigator, A/Prof. Verena Tan (verena.tan@singaporetech.edu.sg).

Will my taking part in the study be kept confidential?

Note: In accordance with SIT's Research Data Management Policy, ALL research data shall be held for 10 years after publication or after the completion of the project, whichever is later.

- This study is anonymous. We will not be collecting or retaining any information about your identity.
- We will not include any information in any publication or presentation that would make it possible to identify you.