SIT IRB Application Number: _____

[Participant Consent Form]

Accurate as of 26/09/2022

Project title: **Effects of Probiotics on Amino Acid Absorption** ("**Research"**)

Please tick accordingly:

□ I voluntarily agree to take part in this Research.

□ I have been given a copy of the Participant Information Sheet for this Research (attached as Appendix 1). The investigators had given me a full explanation on the nature, purpose, location and likely duration of the Research, what I will be expected to do, as well as how my personal data, health information and/or biological materials will be used. I have been given the opportunity to ask questions on all aspects of this Research and have understood the advice and information given.

□ I do not have known food allergy (eggs, soya, peanuts, tree nuts, crustaceans, and/or gluten) and I am aware of the beverage ingredients stated in the Participation Information Sheet.

□ I understand that I am free to withdraw my consent to participate in this Research at any time without justifying my decision and without prejudice and consequence whatsoever. I also understand that my withdrawal of consent does not affect the research information obtained before my consent is withdrawn and such information may be retained and used for this Research

□ I give consent to the use of my personal data for the purpose of this Research. I understand that all personal data relating to this Research is held and processed in the strictest confidence, and in accordance with the relevant data protection laws in Singapore.

□ ~~I agree to donate or gift the biological materials collected for this Research to the PI. I agree that I will not have any right or claim to any share in the commercial gain derived from this Research (if any).~~

□ I agree to be contacted for matters relating to this Research.

□ I allow the subsequent use of my personal data, health information and/or biological materials for future research activities whether or not related to this Research, upon the completion of this Research. *[If the personal data, health information and/or biological materials will not be used for future research under any circumstances, to delete this point entirely.]*

This Research has been explained to me in _____ (state language), which I understand,

by _____ (name of translator).

_____ _____
Name and Signature (Participant) Date

_____ _____
Name and Signature (Consent Taker / Translator) Date

_____ _____
Name and Signature (Witness) Date

For further information on the above research study or to provide feedback, please contact: Dr Verena Tan, Associate Professor (Email: verena.tan@singaporetech.edu.sg)

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Appendix 1 – Participant Information Sheet

Project Title:	**Effects of Probiotics on Amino Acid Absorption** (“**Research**”)
SIT-IRB Application No.:	**2022180**
Principal Investigator’s (“**PI**”) Name and Contact Details:	Dr Verena Tan. Email: verena.tan@singaporetech.edu.sg

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?

The investigational nature of this Research is collaboration between SIT and AMILI Pte Ltd to analyse your blood and stool samples for data on
a) Amount of amino acids absorbed into your bloodstream at 8 different time intervals
b) Profile of different types of microbes living in your gut
After you have consumed commercially available probiotic supplements provided by AMILI, and plant-based protein beverage created in SIT food-grade laboratory.

What is the purpose of this Research?

The purpose of this Research is to investigate the effects of consuming probiotics on the body’s absorption of amino acids when plant protein is consumed. There is a global shift towards plant-based diets for health, environmental, sustainability and animal welfare reasons. On the other hand, probiotics have been associated with numerous health-promoting benefits. However, there is limited scientific understanding of the effects of probiotics on nutrient absorption, particularly protein absorption in plant-based diets. For this research study, we would like to investigate the effects of consumption of probiotics on amino acid absorption of plant protein beverages.

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

You are invited to participate in the research study to investigate the effects of consumption of probiotics supplementation on digestibility of plant protein beverages. You have been invited because you are over the age of 21, able to comply with study procedures and are healthy. However, you are ineligible for the study if any of the following apply: inability to comprehend English, suffering from any chronic medical condition, any medical condition or symptoms relating to the GI tract, antibiotic use, prebiotics, probiotics or synbiotics use, food allergy/intolerance/avoidance, smoking or alcohol consumption.

How many participants will be involved in this Research?

A total of 20 participants will be recruited for the study. The study will be conducted at SIT@Dover for healthy subjects.

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

The entire study will take 10 to 12 weeks to complete. All 4 visits will be conducted in SIT@Dover.
If you agree to be in this Research, you will be asked to follow the schedule below:

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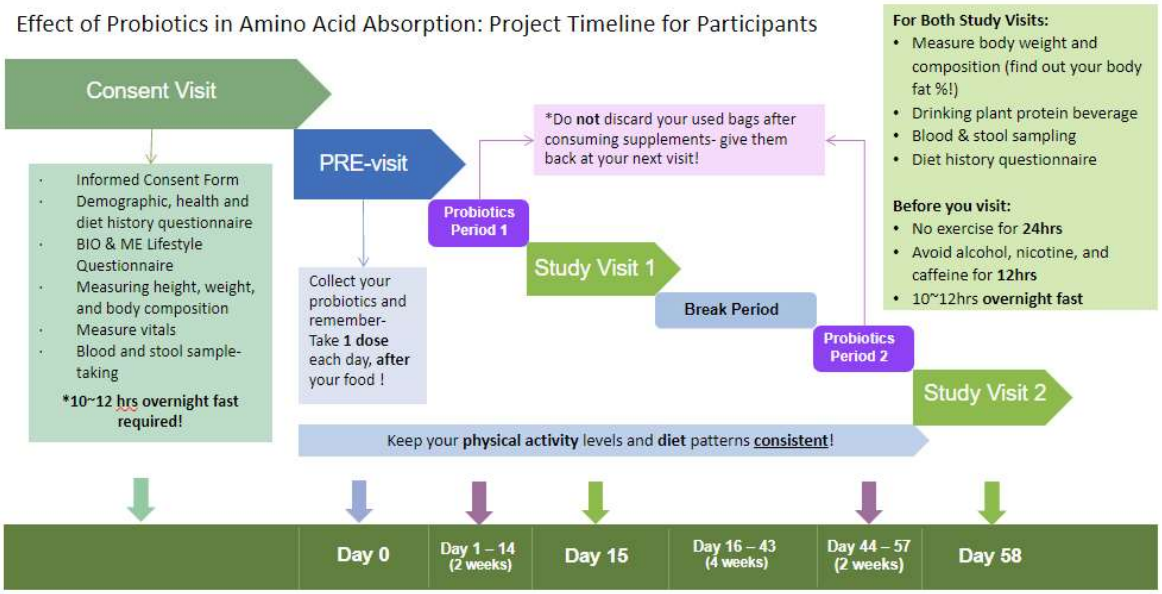

For more details on activities stated in the timeline above:

a) Probiotic Supplements
Study participants will randomly be allocated into either probiotics (PRO) or placebo (PLA) groups. All participants will receive 2 weeks of probiotic supplements over the course of the study, regardless of which group they are allocated to. Probiotics supplements are provided by AMILI and consist of 5 formulations- immunity, well-being, energy, mind and strength. The BIO & ME Lifestyle Questionnaire designed by AMILI and stool sample analysis is to determine the exact type of probiotics supplement which they will receive. Please refrain from consuming any probiotics, prebiotics, synbiotics and/or digestive enzymes throughout the study, from Consent Visit to @nd Study Visit.

b) Height, weight, and body composition
Body composition will be measured using bioimpedance analysis. All measurements will be taken before blood draw.

c) Requirements before Consent and Study Visits

Participants are required to refrain from exercise equal to or more strenuous that moderate-intensity aerobic exercise, defined by HealthHub Singapore as activities which “causes a slight increase in breathing and heart rate… (also) perspiring… such as brisk walking (5 km/hr), leisure cycling (<16 km/hr), leisure swimming, playing doubles tennis, line-dancing”.

d) Diet History Questionnaire
SIT Dietetics and Nutrition students will be engaged to assist participants in conducting diet history questionnaire by the PI, Dr Verena Tan. The diet history information collected will be used to analyze meal patterns and food and beverage intake of participants over the past 6 months.

e) Health Questionnaire
Health Questionnaire will be used to obtain information about participant health history, e.g., past or present medical conditions or disorders, food allergies or intolerances, use of medication or supplements. Participants will also be asked about their lifestyles, such as smoking habits, alcohol consumptions habits, any body weight changes over the past 6 months and exercise type, intensity and frequency over the past 6 months.

f) Plant Protein Beverage
Study participants will be asked to drink 250ml of plant protein beverage within 15 minutes after the first blood draw. Participants asked about any food allergy/intolerance or avoidance they might have

before participation in the study. This is to prevent any discomfort or adverse reactions which may be caused by consuming the plant protein beverage.
Please check that you **do not have any allergy/intolerance/avoidance** of any of the following ingredients used in our plant protein beverage: brown sugar, brown rice protein, yellow pea protein, commercial beverage flavouring, and xanthan gum.

g) Blood Sampling
Participants will have their blood drawn from a vein in their forearm for multiple blood sampling (5ml per collection). A baseline blood sample will be drawn at 0 min, before participants consume the plant protein beverage. The timer will begin for each participant when he or she has taken the first sip of the beverage. Blood samples will be taken at fixed timings, 15, 30, 45, 60, 90, 120, 150 minutes after consuming the plant protein beverage. Participants are required to stay in the laboratory and are not allowed to consume any food during the 3-hour period.

h) Stool Sampling
Stool samples will be collected 1g at a time using a gut microbiome test kit provided by AMILI. These stool samples will allow AMILI to analyze the microbes in participant's gut to determine which is the probiotic supplement type best suited for the participant and observe any changes that come from probiotic supplementation.

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

Personal privacy and confidentiality

This study uses health information that may affect your privacy. To protect your confidentiality, only a unique code number will be used to identify data 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.

Questionnaire

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

Consumption of probiotics supplements and plant protein beverage

Please consult the research team if you experience any discomfort or symptoms after consumption of the probiotics supplements and plant protein beverage. The ingredients used in the plant protein beverages do not contain known allergens. Nonetheless it is important that you declare any food allergy/intolerance to us before participation in the study to avoid potential adverse reactions or discomfort.

Collection of blood

Taking blood may cause momentary discomfort, pain, bleeding, bruising or swelling at the site of the needle stick. Rarely, taking blood may cause fainting or infection. If possible, the research blood sample(s) will be collected at the same time you have blood drawn for clinical care or through an existing catheter already inserted into a vein.

All blood samples will be used for the sole purpose of research only. Any stored blood samples will be discarded or destroyed after the completion of study or upon study subjects' withdrawal from the study.

What are the expected benefits from participating in this Research?

Your participation will enable us to understand the effects of probiotics supplementation on digestibility of plant proteins. The findings of the study can help to shape the functionalization of future food for people looking to optimize protein absorption or helping people with protein deficiency/malabsorption.

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 the PI in charge of this Research at all times. If you feel any discomfort, please notify the PI immediately. 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. By signing this Participant Consent Form, you will not waive any legal rights or release the researchers from liability for negligence.

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

There are no anticipated expenses to be incurred by the research subject for participating in the research.

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

Research subjects will be reimbursed with a $100 voucher upon completion of study.

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 personal data such as your name, Student ID, SIT email address, age, gender, contact number 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 information such as height, weight, body composition, resting heart rate, blood pressure, health and dietary history 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.

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:

a) SIT will collect your blood and stool samples for the purpose of this Research.

b) The PI will only disclose your biological materials to members of the research team on a need-to-know basis if necessary.

c) All individually-identifiable biological materials will be coded (i.e. only identified with a code number) at the earliest possible stage of this Research. Your personal data will be kept separately from your blood and stool samples. The link between your personal data and the code number will be kept confidential by the PI or a trusted third party.

(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 that would make it possible to identify you.

(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. Your personal data/health information/biological materials will not be stored for future biomedical research. For biological materials, they will be destroyed and discarded upon analysis.

Under what circumstances will I be contacted for further consent?

You will be contacted for further consent, including but not limited to changes in the proposed research, serious adverse events that would lead to a change in the proposed research, and any other circumstances which could be specific to a particular research proposal.]

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

During the course of the study, there is a possibility that we might unintentionally come to know of new information about your health condition from the analysis from your health information/blood/stool or other procedures that is/are conducted as part of the study. These are called “incidental findings”. “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. These findings may affect your current or future life and/or health insurance coverage.

Examples of potential incidental findings that may be discovered during the course of this study may include but are not limited to metabolic disorders relating to protein and glucose metabolism or other diseases affecting metabolic pathway.

You will be asked to indicate whether you wish to be re-identified and notified in the case of a clinically significant incidental finding that is related to you.

If you agree to be re-identified and notified, your study doctor/a qualified healthcare professional will explain the incidental finding to you and discuss and advise you on the next steps to follow. For this purpose, please inform the Principal Investigator or any of the study contact persons listed in this document whenever there are changes in your contact details. You may wish to do more tests and seek 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.

Can I withdraw my consent to participate in this Research?

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You may withdraw your consent to participate in this Research at any time. Please contact Dr Verena Tan, PI of the Research 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?

Please contact Dr Verena Tan, PI of the Research via email (verena.tan@singaporetech.edu.sg) if you wish to obtain more information or provide feedback in relation to this Research.