PARTICIPANT INFORMATION SHEET

You are invited to participate in a research study. This information sheet provides you with information about the research study. Where "personal data" is used, it means data about you which makes you identifiable: (i) from such data or (ii) from such data and other information which the National University of Singapore (NUS) has or is likely to have. The Principal Investigator (the research doctor or the person in charge of this research) or his/her representative will also describe this research to you and answer all your questions. Read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

PART I: General Information

1. **Protocol title:** Dietary Intervention on Atopy (NUS-IRB-2024-28)

2. **Principal Investigator and co-investigators, with the contact number and address of organisation:**

Principal Investigator
Associate Prof. Chew Fook Tim
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Co-investigator
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Molecular Immunology Laboratory,
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Tel: 65161685; email: nus.allergy.study@nus.edu.sg

3. Whom should I call if I have any questions or problems?

Please contact the Principal Investigator, Assoc Prof. Chew Fook Tim at **telephone** 65161685 (between 9.00 AM – 6.00 pm Monday to Friday) and **email** at dbscft@nus.edu.sg for all research-related matters and in the event of research-related injuries.

This study has undergone an ethics review by the National University of Singapore Institutional Review Board (NUS-IRB). For an independent opinion regarding the research and the rights of research subjects, or if you have complaints about the research, you may contact a staff member of the NUS-IRB (at telephone (+65) 6516 1234 [Mondays to Thursdays from 8.30am to 6pm, and Fridays from 8.30am to 5.30pm, except public holidays] or email at irb@nus.edu.sg).

4. Who can participate in the research? What is the expected duration of my participation? What is the duration of this research?

You may participate in the research if you are **between 21 and 65 years old** and having a personal symptomatic history of an atopic dermatitis itchy rash.

The study requires you to attend **five** visit (1 screening and 4 study visits) that will take approximately **1 hour 30 minutes each**. The total duration of the study will be 13 weeks, not including the screening visit. At each visit, you will need to complete all questions in a provided questionnaire, undergo a skin physiology measurement to assess skin pH, sebum level, hydration, and trans epidermal water loss, undergo basic anthropometric measurements for height, weight, body composition, and blood pressure, provide a 20 mL whole blood sample, and provide a stool swab. You cannot take part in the study if you have a needle phobia or if you are currently having food allergy or uncomfortable in answering the mandatory questions in the questionnaire. In addition, food logs will be collected from you at multiple time points. You may be assigned to a whole-meal intervention where meals will be provided for lunch and dinner daily for the entire 2-month intervention period.

You will only be allowed to participate **once** throughout the whole period of this study. As meal provision may be provided locally, participants who will be travelling out of Singapore during the study period will not be eligible to participate in this study. Participants who are on regular strong use of medication (western and/or traditional), therapies, alternative medications, or concurrently participating in other research studies are not encouraged to participate in this study. You should not be applying any moisturizer, cosmetics, and/or any topical cream on your skin throughout the entire duration of the study. The research team will advise you accordingly based on your eczema condition should you require the use of any anti-itch or moisturizing medication during the course of this study.

A member of the research team has discussed with you the requirements for participation in this study. It is important that you are completely truthful with the staff about your past medical history as well as any symptoms experienced during the study. It may be harmful to you or other people who participate in this

study if you are not truthful with the staff. You should not participate in this study should you not meet all qualifications.

Participants must meet all the inclusion criteria to participate in this study:

Inclusion criteria are:

- Presence of current, mild-to-moderate atopic dermatitis/eczema at the flexural areas
- 21 to 65 years of age (inclusive) at screening
- Must be English-literate and able to give informed consent in English
- Be residing in Singapore and will not be travelling outside of Singapore during the study period
- Reliable and willing to follow study procedures and be available for the duration of the study
- Non-smokers (tobacco and e-cigarette)
- Non-drinker (no regular or frequent consumption of alcohol)
- Overtly healthy with no pre-existing medical conditions (e.g., diabetes, hypertension, cancer, blood disorders, degenerative/liver/autoimmune/immune/renal diseases, or psychiatric conditions)
- No food allergies to test foods
- No needle phobia
- Be willing to follow the instruction provided by the investigators on the use of any moisturiser, cosmetics, and/or topical cream on the skin throughout the entire duration of the study.

You cannot participate in this study if you are or have:

- Concurrent participation in other research studies
- Pregnant or lactating
- Known or ongoing psychiatric disorders within 3 years
- Known severe nutritional deficiency
- Vegetarian or vegans (as meat will be included in the diet)
- Individuals who made a significant dietary change in the past 12 months
- Having a pre-existing dietary restriction that would interfere with the adherence to a whole diet meal
- Regular use of strong medication (western and/or traditional), therapies, and alternative medications
- Regular nutritional supplements in the past 12 months
- Regular consumption of oral contraceptive pills and/or steroid hormones
- Antibiotic use in the past 2 months
- Any long-term hospitalisation or surgery during the 6 months before enrolment in study
- Significant change in weight (+/- 5.0%) during the past month
- History of bleeding diathesis or coagulopathy (or any bleeding disorders)
- Having donated blood of more than 500 mL within 4 weeks of study enrolment

5. What is the approximate number of research subjects involved?

We aim to recruit 110 participants to this study.

6. What will be done if I take part in this research study?

This research study involves a total of **five** on-site visits (1 screening visit and 4 study visits); each scheduled approximately one month apart. The different parts of the research study are described below.

Screening

The research team will first contact you over phone call to explain the study details and interview you on your demographic background, health and medical history, medications, use of tobacco and alcohol, and dietary habits (information related to the inclusion and exclusion criteria). No in-person visit is required.

However, if you fulfilled the basic eligibility criteria, you will be contacted further for face-to-face interview. During the actual screening, it will involve a face-to-face visual screening for the presence of atopic dermatitis (AD) rash and clarifying questions for the inclusion and exclusion criteria for the study in more detail. If you are selected for the study, you will be contacted further for the first study visit.

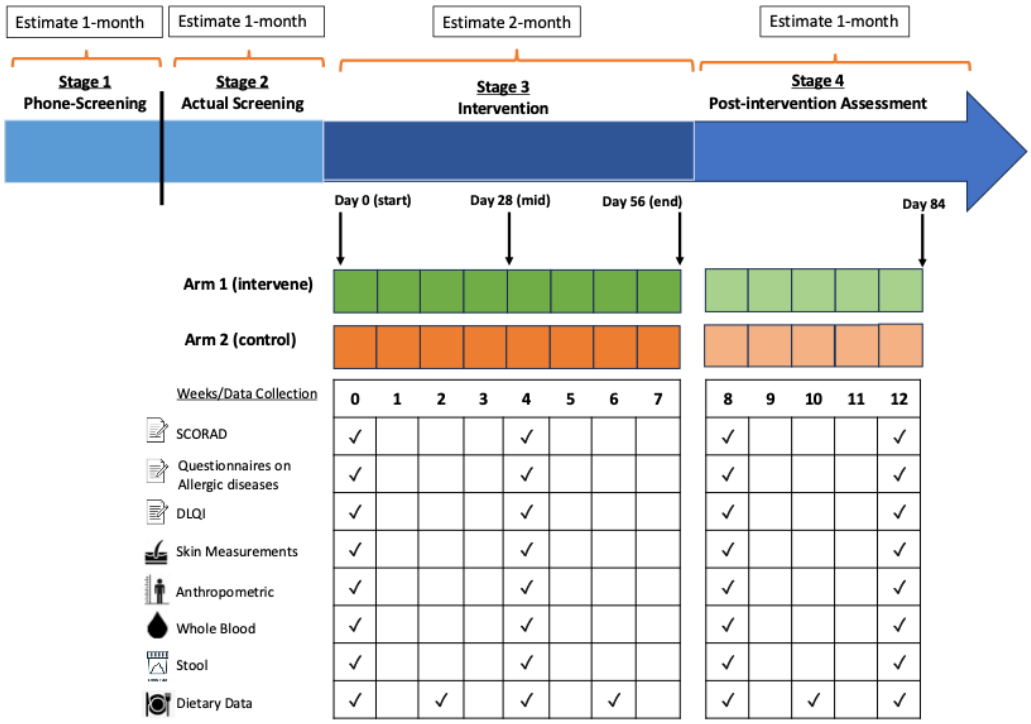
Study Visit (s)

The research team will arrange an appointment for you to attend the study at a suitable venue (NATIONAL UNIVERSITY OF SINGAPORE (S13), Level 3, 1 Science Drive 3 Singapore 117550). All study procedures will be performed by trained staff.

To summarise, you will undergo the following procedures in this research:

1. Questionnaires: (i) 1st Study Visit only: ISAAC questionnaire for basic demographic information; (ii) All Study Visits: Drug Usage Questionnaire, Dermatology Quality of Life Index Questionnaire and Asthma Quality of Life Questionnaire (only for those who report as having asthma).
2. Eczema assessment using validated questionnaire tool (Scoring Atopic Dermatitis [SCORAD])
3. A skin physiological measurement involving pH, sebum level, hydration, and water loss
4. Anthropometric measurement
5. Blood collection
6. Nutritional counselling (only for those assigned into the diet group)

The total time you will spend at the study will take about **1hr** to **1 hour 30 minutes** for each study visit. For more information, please kindly refer to the proposed systematic flow of the entire dietary intervention timeline image below.



- **ISAAC questionnaire** – The survey questionnaire you need to complete relates to you and your family history of allergy and its related symptoms, personal lifestyle preferences, dietary habits, and basic demographic information such as age, gender, socioeconomic status, and parental education level. This will only be done during the first study visit and not required for remaining study visits.

- **Drug usage questionnaire** – This short survey asks about the usage of 17 types of drugs related to allergy and its related diseases, over the past 4 months. It will be administered during every study visit.

- **Dermatological Quality of Life Index questionnaire** – This is a ten-question questionnaire used to measure the impact of skin disease on the quality of life of an affected person.

- **Asthma Quality of Life Index questionnaire** – This is a patient-reported questionnaire that measures the impact of asthma on daily life by assessing functional impairments in four main areas: symptoms, activity limitations, emotional function, and environmental stimuli. This questionnaire is only applicable to those diagnosed with asthma.

- **Eczema assessment** – Trained research personnel will assess your eczema/atopic dermatitis condition accordingly with a validated clinical rubric known as SCORAD (Scoring Atopic Dermatitis). There is no need to remove any clothing during the entire skin assessment, and no photographs will be taken from you.

- **Skin physiological measurement**– This test is carried out on the face (cheek), forearms, and two main lesional areas affected by eczema/atopic dermatitis, particularly the flexural areas including the folds of the elbows, behind the knees, in front of the ankles, or around the neck and face. All

probes used for skin measurement will be sterilized with alcohol swabs before and after each measurement.

- **Blood samples** – A 20 mL of blood sample (with allocations of 5 mL, 5 mL, and 10 mL) will be collected from you, which will be used to assess lipid levels, immune cell counts, serum cytokine levels, and extract peripheral blood mononuclear cells.
- **Stool samples** – Stool sample collection kits will be issued, and you are required to bring back the stool samples on your next visit. Stool samples will be used for gut microbiota analysis.

Intervention

You will be randomly assigned to either the diet (intervention) group or control group.

If you are randomly assigned to the diet group, you will be provided with bento-styled meals for lunch and dinner daily during the 2-month intervention period. The meals will encompass a variety of nutrient-rich ingredients, including whole grains, lean proteins, fruits and vegetables, and healthy fats. The meals are also designed in a convenient bento-style format. The food will be prepared and delivered by our partnered licensed food caterer company. The research team will provide you with periodical reminders regarding the transport and consumption of your meals whenever necessary.

However, you will neither receive the meals provided by the research team nor will you receive any nutritional advice if you are randomly assigned to the control arm. Instead, you will continue to follow and maintain your usual dietary habits throughout the study period.

All participants will be required to maintain detailed food logs for three days per week – specifically, two selected weekdays and one weekend day – every other week throughout the study duration. The estimated duration required to complete the food log for each meal is around 10 minutes. Food logs will be collected at multiple time points, including baseline (week 0) and subsequent intervals at 0,2,4,6,8,10 and 12 weeks. Food logs will be regularly reviewed to assess your adherence to the prescribed healthy eating dietary pattern.

Post-intervention Assessment (follow-up)

If you are assigned to the diet group, the provision of bento-styled meals will conclude immediately after the 2-month intervention period. However, it is imperative that you continue to adhere closely to the provided nutritional advice for an additional month. Regardless of your group assignment, you are required to attend the final study visit.

7. Will there be reimbursement for reasonable transport costs and time spent from my participation?

You will be reimbursed for your time and transport to participate in this study. The reimbursement will be made only on completion of the study. In the event the study ends early for a participant, the reimbursement will be pro-rated for the actual time and travel involved. However, no pro-rated reimbursement will be provided if your participation is withdrawn due to non-compliance issue as determined by the research team and investigators. Upon the completion the entire study, you will be paid a $280 SGD as described below:

Visit	Amount to be reimbursed	Mode of reimbursement
Actual Screening (first visit)	$20.00	Cash via PayNow
Visit 1 (pre-intervention)	$50.00	Cash via PayNow
Visit 2 (mid-intervention)	$50.00	Cash via PayNow
Visit 3 (post-intervention)	$80.00	Cash via PayNow
Visit 4 (follow-up; final visit)	$80.00	Cash via PayNow
Total amount	**$280.00**	

8. How will my privacy and the confidentiality of my research records be protected?

NUS has established data management policies and rules for protection of the personal data of human research subjects in NUS studies, including the collection, use and storage of such data. Additionally, our researchers are required to comply with the Human Biomedical Research Act (HBRA) and other applicable laws. Under the HBRA and the Personal Data Protection Act (PDPA), researchers must take all reasonable steps and safeguards as needed to protect individually identifiable information or material against accidental or unlawful loss, modification or destruction, or unauthorised access, disclosure, copying, use or modification.

For purposes of validating the research findings and supporting future research work, research data (without personal identifiers) used in any publication will be kept for a minimum of 10 years before being discarded in accordance with the NUS Research Data Management Policy.

PART II: Information on this Human Biomedical Research

9. What is the nature of this biomedical research?

This research is a clinical study, and the aim of this research study is to assess the effectiveness of an improved dietary pattern of lowered saturated fats, higher wholegrains, fruit, and vegetables in reducing the severity of atopic dermatitis (eczema) symptoms among individuals with existing volunteers from Singapore. In this way, we will be able to determine the effectiveness of a healthy and balanced dietary intervention on atopic dermatitis in our local population which is useful in improving public health.

10. What is the purpose of this biomedical research?

The main objective of this study is to assess the effectiveness of a dietary pattern characterized by lower saturated fats, higher wholegrains, fruit, and vegetables in reducing the severity of atopic dermatitis in young Singapore adults over a 2-month intervention period. The study also aims to evaluate if the improved dietary pattern impacts on the quality-of-life, skin barrier functions, immunity functions, and gut microbiota composition and diversity.

11. What are the possible risks, discomforts or inconveniences to me if I participate in this research?

Stool collection and skin physiology measurements are unlikely to cause discomfort and are minimally invasive techniques. Skin physiology measurements are taken by probes and will be sanitised for each participant. Stool collection kits are given to the participants for use at their best convenience.

The process of blood collection may cause some discomfort and pain at the site of needle insertion. Occasionally, some individuals may experience fainting or a vasovagal response during or after blood collection. These are some common and expected side effects of the procedure. Participants should be informed about this aspect beforehand. Bruising and bleeding at the site of blood collection are potential side effects. This occurs when blood leaks into the surrounding tissues, leading to discoloration and swelling. These effects are usually mild and temporary. If a participant experiences serious effects from the blood collection, the participant will be immediately transported to NUH A & E (within proximity to study site). At NUH emergency, the team of doctors on duty will assess and provide medical support. In the case of a collapsed vein, our trained phlebotomists will attempt to draw blood from a different vein.

Standard meal provided in this study will be prepared by a licensed food catering service. In a rare unfortunate event, food allergy or acute gastroenteritis is possible. In such cases, you should contact our research coordinator or the Principal Investigator as soon as possible. Medical attention will be given immediately, and you will be directed to proper health treatment or admitted to hospital for treatment.

There is a potential risk of discomfort and exacerbation of eczema rash among participants due to the lack of application of moisturizers and/or topical creams throughout the study duration. To mitigate the risk of discomfort and exacerbation of eczema rash, participants will be advice accordingly to manage eczema symptoms, such as avoiding known triggers and maintaining proper hydration. Regular monitoring of participants' skin condition will be conducted, and any signs of discomfort or exacerbation of eczema rash will be promptly addressed to ensure participant comfort and well-being.

12. What benefits can I expect from participating in the research?

There is no direct medical benefit from participation in this study. Study procedures will be provided at no cost to the participant. A skin physiology measurement will be conducted and explained which may be beneficial to participants in understanding their skin health. The results of the skin physiology measurement will be made known to you before you leave the study. Apart from this, we will not be reporting back results of analyses or future analyses of your data or samples, unless these results are of serious health importance.

13. Are there any alternative procedures or treatments available to me? What are the potential benefits and risks of such alternatives?”

There are no alternative procedures or treatments available.

14. Do I have to incur any expenses by participating in this research?

If you take part in this study, you will not have to pay for any procedures. However, you may incur transport expenses to the study venue.

15. What will happen to the biological material taken from me?

If you consent, the blood and stool samples obtained from you will be de-identified and stored at the Allergy and Molecular Immunology Laboratory (Lee Hiok Kwee Functional Genomics Laboratories, Block S2, Level 5, 14 Science Drive 4, Singapore 117543) for five years upon the completion of this research study. Stored samples may be used in future biomedical research, subject to an Institutional Review Board's approval. *There are 2 types of future studies:*

Type a) Involving the use of your biological material without the need to recontact you.
Type b) Studies that need some information from your end.

For Type a studies (the studies that only require the use of your biological material), your consent is requested for in the consent form. If you do consent for the use of your biological samples for future studies, they will be used in research involving allergies and skin conditions. Your samples will be stored using only study codes in a locked freezers and accessible only by authorised personnel. No tissues or primary data will be transferred to other institutions.

However, if you do not consent to use your samples in the future, leftover samples will be destroyed at the end of this study. No further consent will be sought from you for the use of your samples at any later time.

For Type b studies, you will be re-contacted if you consent for participation in studies that may require further health/lifestyle information from you.

16. Will my participation in this research involve the use of any information that will identify me?

Your personal data (i.e., name, email, phone number and residential address) will be collected in this study for the purpose of communication. If you are assigned to the diet group, your residential address is collected to facilitate the delivery of meals to your home as part of the dietary intervention.

17. Will any identifiable information obtained from me be used for future biomedical research?

As mentioned in paragraph 15, there might be future research that that requires some health/lifestyle information from you (Type b studies). If you consent to be re-contacted in the consent form, we might re-contact you to invite you participate in any of our future studies. Your personal data (i.e., name, email, phone number, and residential address) will be retained for a period of at least 10 years by the trusted third party so that we may re-contact you (only if you consent to this) for participation in future research and/or follow-up in this study. Your identifiable information will never be used for any other purpose.

18. How will my personal identifiers collected from me be kept confidential?

Only the principal investigator, co-investigators, as stated in question 23, will have access to your personal data (e.g., names and contact information). This data will not be released to any other person, unless required by applicable laws and regulations e.g., Infectious Diseases Act. Your personal data will never be used in a publication or presentation. To protect your confidentiality, your biospecimens and data will to the extent feasible during the study, be coded (i.e., only identified with a code number). The link between your personal data and the code number will be kept confidential by the principal investigator or a trusted third party.

We will do our best to protect your data and biospecimens during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorised people might access your data and biospecimens. In either case, we cannot reduce the risk to zero.

19. Can I withdraw my consent to the research at any time?

You can withdraw from the research at any time without giving any reasons, by informing the principal investigator verbally or in writing. Please note that the withdrawal of consent does not affect the research information obtained before the consent is withdrawn and such information may still be retained and used for research if you permit. There will be no penalties imposed on you should you withdraw your consent to participate in this research. You are entitled to refuse to participate or discontinue participation at any time in this research. Upon withdrawal, your data and your samples would be destroyed accordingly.

20. Will I be re-identified in the event of incidental finding(s) arising during the biomedical research?

It is possible that during the research we may find you have pre-existing medical issues that are unrelated to our research. These are called “incidental findings”. “Incidental findings” are findings that have potential health or reproductive importance to participants like you and are discovered in the course of conducting the study, but are <u>unrelated</u> to the purposes, objectives or variables of the study.

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. The discovery of an incidental finding, at the discretion of the University, will be communicated to you for the purpose of seeking medical advice or treatment. In the event that you have indicated not to be re-identified and notified, but the University has determined that the incidental finding is of clinical significance, you may still be contacted to decide if you wish to be notified of the incidental finding at that time.

21. Under what circumstances will I be re-contacted for further consent?

We do not anticipate any significant changes to our study protocol that would require re-consent.

<u>PART III: Information on the Removal and Use of My Tissue(s) for this Research</u>

22. What are the tissue(s) that will be taken from me and what will they be used for?

There will be four study visits and during each visit, a total of 20 mL whole blood and 500 mg stool samples (faecal) are collected through venepuncture

procedure and a standard stool collection kit. The blood sample collected will be used for a thorough analysis of lipid levels, immune cell counts, serum cytokines, and gene expression profiling, which is done by service providing companies. Your consent for the use of leftover samples in future research endeavours will be sought, and you will have the option to opt-in or opt-out as per your preference. Otherwise, leftover blood and faecal samples will be destroyed at the end of the study. Stool samples may undergo processing using commercial DNA kits. This process enables us to conduct 16S rRNA gene sequencing, a technique that helps identify and quantify different bacterial taxa within the microbiota. These samples may also be subject to metagenomic analysis, allowing us to study the genetic material of the entire microbial community.

23. Will my personal data be shared and/or processed for use in research?

Your personal data will only be shared and processed for use in research purposes with your explicit consent. We adhere to strict confidentiality measures and will not disclose your personal information without your prior authorization. Any data shared for research purposes will be anonymized or coded to protect your privacy. Additionally, all research activities involving your personal data will be conducted in compliance with applicable data protection laws and regulations. We prioritize transparency and will provide you with detailed information about how your data will be used and any potential risks involved before seeking your consent for its processing in research.

24. Will my personal data be processed overseas for use in research?

Your personal data will only be processed overseas for use in research if it is necessary for the specific aims of the study and with your explicit consent. We prioritize the protection of your personal information and ensure that any overseas processing complies with applicable data protection laws and regulations. Additionally, we take measures to safeguard your data during international transfer, such as utilizing secure encryption methods and selecting reputable partners who adhere to strict privacy standards. The overseas recipients of your personal data are bound by legally enforceable obligations to protect your personal data to a standard comparable to the data protection laws of Singapore.

25. Will my tissue(s) be used for any purpose other than research?

The biological samples collected from you (blood and faecal) will not be used for any purpose other than research.

26. What risks, discomforts and inconveniences will I expect if my tissue(s) is/ are removed from me?

Some individuals may also experience fainting or a vasovagal response during or after blood collection. As the blood collection procedure will only be conducted in a room designated for blood draw, and you will be sitting comfortably on a chair throughout the procedure. There are beds in the room, and you can use them to rest if you experience faint spells during the event. Some discomfort, pain, bleeding or bruising at the site of the needle stick may occur during collection of blood samples. There is a risk of vein collapse during venepuncture. In the case of a collapsed vein, phlebotomists will attempt to draw blood from a different vein.

27. Does this study involve the removal of human tissues from persons who lack mental capacity or understanding and intelligence to consent to the donation of their tissues for the study? If so, what are the proposed area(s) of research approved by the Institutional Review Board (IRB), where the IRB has waived the requirement that the removal of my tissue(s) be for therapeutic or diagnostic purposes?

No, this study will not involve the removal of human tissues from individuals who lack the mental capacity or understanding and intelligence to consent to the donation of their tissues.

28. Will I still retain my rights to my tissue(s) after it has/ have been removed from me?

Donation of your tissues is voluntary. By donating your tissues, you will relinquish your rights to your tissues and any intellectual property rights that may be derived from the use of your tissues.

29. Do I have to incur any expenses if I donate my tissue(s) for this research?

You do not have to incur any expenses for donating tissues in this research.

30. If I am injured as a result of donating my tissue(s), what are the compensation and treatments available to me?

If you follow the directions of the PI in charge of this research study and you are physically injured, the NUS 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.

31. Will my donated tissue(s) be used in any ways that can identify me?

Your personal data (i.e., name, email, phone number, and residential address) will be collected in this study for the purpose of communication. The samples will be coded immediately and there will be no attempts to reidentify you with the sample code. The samples will never be studied in an individually identifiable form. The research team will never use any identifiable information to store or transfer the samples.

32. Will the records that identify me in relation to my tissue(s) donation be kept confidential?

To protect your confidentiality, your blood and faecal samples will be coded (i.e., only identified with a code number). All personal data (e.g., names and contact information) will be kept separate from your blood and faecal samples. The link between your personal data and the code number will be kept confidential by the faculty which is the trusted third party. The data will be stored in password-protected files under a data manager of the trusted third party.

33. Will the identifiable information obtained from me in the course of tissue donation be used for future research?

If you consent, your personal data (i.e., name, email, phone number, and residential address) will be retained for a period of at least 10 years by a trusted third party so that we may re-contact you for participation in future research (allergy or skin condition research) and/or to communicate with you regarding incidental findings. If you agree to be re-contacted for future related studies your

consent will be sought for that particular study. The identifiable information will not be used in anyway in future research other than to re-contact you.

34. What will happen to the tissue(s) taken from me upon completion of the research?

Leftover blood and faecal samples will be destroyed at the end of the study if you did not give consent for their use in future related research.

As mentioned in paragraph 15, future research that is of Type a) Involving the use of your biological material without the need to re-contact you. For these studies, we only require the use of your biological material, your consent is requested in the consent form. If you consent for the use of your biological samples for future studies, they will be used in research involving allergies and skin conditions. Your samples will be stored using only study codes in a locked freezers and accessible only by authorised personnel. No tissues or primary data will be transferred to other institution. No further consent will be asked at any later time for the use of your biological samples.

35. Will my tissue(s) be used in restricted human biomedical research?

Your tissue(s) will not be used in restricted human biomedical research involving human-animal combinations.

36. Will my tissue(s) be exported overseas or removed from Singapore?

Your tissue may be exported or removed out of Singapore in order to perform targeted genotyping, as the service providers maybe located in regions other than in Singapore. Any export of samples will be done only if you expressly agree to this.

37. Will I be re-identified in the case of incidental finding(s) arising from the use of my tissue(s) in future research?

It is possible that during the research we may find you have pre-existing medical issues that are unrelated to our research. These are called “incidental findings”. “Incidental findings” are findings that have potential health or reproductive importance to participants like you and are discovered in the course of conducting the study, but are <u>unrelated</u> to the purposes, objectives or variables of the study.

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. The discovery of an incidental finding, at the discretion of the University, will be communicated to you for the purpose of seeking medical advice or treatment. In the event that you have indicated not to be re-identified and notified, but the University has determined that the incidental finding is of clinical significance, you may still be contacted to decide if you wish to be notified of the incidental finding at that time.

38. Can I withdraw my consent to the removal of my tissue(s) and/or use of my tissue(s) in research at any time?

You can also withdraw from the research at any time without giving any reasons, by informing the principal investigator and all your tissue(s) collected will be discarded. However, this only applies if the tissue is individually-identifiable and has not been used for research, or has been used for research but the PI has

determined that the sample quality does not suit the research purpose. Please also note that the withdrawal of consent does not affect the research information obtained before the consent is withdrawn and such information may still be retained and used for research. There will be no penalties or damages imposed on you should you withdraw your consent to participate in this research.

39. Will I be re-contacted for further consent for the use of my tissue(s)? If so, under what circumstances?

We do not anticipate any significant changes to our study protocol that would require re-consent.

Protocol title: Dietary Intervention on Atopy

Participant copy

Principal Investigator with the contact number and organization:

Associate Prof. Chew Fook Tim
Allergy Molecular Immunology Laboratory,
Department of Biological Sciences, Faculty of Science
National University of Singapore.
Tel: 6516 1685; email: dbscft@nus.edu.sg

Part A. I hereby acknowledge that:

1. My signature is my acknowledgement that I have agreed to voluntarily take part in the above research.

2. I have received a copy of this Participant Information Sheet that explains the use of my human biological material and data in this study.

3. By signing this consent form, I understand its contents and agree to donate my human biological material and data for the use purpose of this research. I confirm that I consent to the collection, disclosure and processing of my *human biological material and data* for the purposes of the study.

4. I can withdraw from the research at any point of time by informing the Principal Investigator although if I have donated tissue for the research, I can only withdraw my consent to use my tissue if the tissue is individually identifiable and has not been used for research or it is practicable to discontinue further use of my tissue for research. I am aware that that the withdrawal of consent does not affect the research information obtained before the consent is withdrawn and such information may still be retained and used for research.

5. I will not have any financial benefits that result from the commercial development of this research.

Part B. For human biological materials and data (including personal data) collected **for use in future research**, please select 1 of the four choices below:

☐ I agree to donate my *human biological material and data* collected for this research to be used in future research OR

☐ I agree to donate my *human biological material and data* collected for this research to be used in future research. However, I would like all personal data removed from my biological samples so that no one can link the sample to me OR

☐ I agree to donate my *human biological material and data* collected for this research to be used in future research which may include testing and development by commercial firms. However, I would like all personal data removed from my biological samples so that no one can link the sample to me OR

☐ I do not agree to donate my *human biological material and data* collected for this research to be used in future research and would like to have my leftover biological samples destroyed after the completion of this research.

Part C. For human biological materials and data (including personal data) collected **for overseas exportation**.

6. I *agree / do not agree* that my data and the research data derived from the research may be processed and transferred to any overseas recipient. Such recipients are bound by legally enforceable obligations to protect my personal data to a standard comparable to the data protection laws of Singapore.

7. I *agree / do not agree* for my leftover human biological materials to be exported or removed out of Singapore.

Part D. For purposes of **re-contact:**

8. I *agree / do not agree* to be re-contacted for future related studies. I understand that future studies will be subject to an Institutional Review Board's approval.

9. I *agree / do not agree* that I may be contacted if a medical issue is found during the course of this study or in future research, in order to facilitate my seeking proper medical advice. I understand that my participation in the research is not considered medical treatment, and that the researchers are not qualified medical practitioners able to provide diagnoses.

_____ _____

Name and Signature (Research Subject) Date

I, the undersigned, certify to the following:

(a) I am 21 years of age or older.
(b) I have taken reasonable steps to ascertain the identity of the research subject.
(c) To the best of my knowledge, the research subject had the study fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.
(d) I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

_____ _____

Name and Signature (Witness) Date

_____ _____

Name and Signature (Consent Taker) Date

Protocol title: Dietary Intervention on Atopy

Investigators copy

Principal Investigator with the contact number and organization:
Associate Prof. Chew Fook Tim
Allergy Molecular Immunology Laboratory,
Department of Biological Sciences, Faculty of Science
National University of Singapore.
Tel: 6516 1685; email: dbscft@nus.edu.sg

Part A. I hereby acknowledge that:

1. My signature is my acknowledgement that I have agreed to voluntarily take part in the above research.

2. I have received a copy of this Participant Information Sheet that explains the use of my human biological material and data in this study.

3. By signing this consent form, I understand its contents and agree to donate my human biological material and data for the use purpose of this research. I confirm that I consent to the collection, disclosure and processing of my *human biological material and data* for the purposes of the study.

4. I can withdraw from the research at any point of time by informing the Principal Investigator although if I have donated tissue for the research, I can only withdraw my consent to use my tissue if the tissue is individually identifiable and has not been used for research or it is practicable to discontinue further use of my tissue for research. I am aware that that the withdrawal of consent does not affect the research information obtained before the consent is withdrawn and such information may still be retained and used for research.

5. I will not have any financial benefits that result from the commercial development of this research.

Part B. For human biological materials and data (including personal data) collected **for use in future research**, please select 1 of the four choices below:

☐ I agree to donate my *human biological material and data* collected for this research to be used in future research OR

☐ I agree to donate my *human biological material and data* collected for this research to be used in future research. However, I would like all personal data removed from my biological samples so that no one can link the sample to me OR

☐ I agree to donate my *human biological material and data* collected for this research to be used in future research which may include testing and development by commercial firms. However, I would like all personal data removed from my biological samples so that no one can link the sample to me OR

☐ I do not agree to donate my *human biological material and data* collected for this research to be used in future research and would like to have my leftover biological samples destroyed after the completion of this research.

Part C. For human biological materials and data (including personal data) collected **for overseas exportation**.

6. I *agree / do not agree* that my data and the research data derived from the research may be processed and transferred to any overseas recipient. Such recipients are bound by legally enforceable obligations to protect my personal data to a standard comparable to the data protection laws of Singapore.

7. I *agree / do not agree* for my leftover human biological materials to be exported or removed out of Singapore.

Part D. For purposes of **re-contact:**

8. I *agree / do not agree* to be re-contacted for future related studies. I understand that future studies will be subject to an Institutional Review Board's approval.

9. I *agree / do not agree* that I may be contacted if a medical issue is found during the course of this study or in future research, in order to facilitate my seeking proper medical advice. I understand that my participation in the research is not considered medical treatment, and that the researchers are not qualified medical practitioners able to provide diagnoses.

_____ _____

Name and Signature (Research Subject) Date

I, the undersigned, certify to the following:

(e) I am 21 years of age or older.

(f) I have taken reasonable steps to ascertain the identity of the research subject.

(g) To the best of my knowledge, the research subject had the study fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.

(h) I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

_____ _____

Name and Signature (Witness) Date

_____ _____

Name and Signature (Consent Taker) Date