PATIENT INFORMATION SHEET

(*for adult subjects and interventional studies*)

1. Title of study: Immunomodulatory, Oxidative Damage Protection and Genomic Stability Effects of IgCo colostrum milk among Older Adults Subjects.

2. Introduction:

You are invited to participate in a research study. Before participating in this study, it is important that you take time to read and understand the information in this Information Sheet. Please take your time to read through and consider this information carefully before you decide if you are willing to participate. Ask the study staff if anything is unclear or if you would like more information. To participate in this study, you may be required to provide the information on your health history; you may harm yourself if you are not truthful with the information provided.

Your participation in this study is voluntary. You do not have to be in this study if you do not want to. If you agree to take part, then you will be asked to sign the "Informed Consent Form". You will be given a copy of the form and this Information Sheet. If you volunteer to be in this study, you may withdraw from it at any time without penalty. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are otherwise entitled.

This study has been approved by the Research Ethics Committee, Universiti Kebangsaan Malaysia.

3. What is the purpose of the study?

In this study, we propose to use IgCo milk enriched with colostrum to modulate cognitive effect, immune function, genomic stability and overall health and wellbeing in older adults (age 50-69 years old). This research is necessary because adults aged between 50-69 years old is the most susceptible group for mild cognitive impairment and lifestyle intervention is critical at this point of time to reverse and delay signs of ageing. A total of 66 subjects like you from Selangor and Kuala Lumpur will be participating in this study. The whole study will last about 3 months. Your participation is needed throughout the 3 months duration.

4. What is IgCo colostrum milk?

IgCo colostrum milk is a kind of milk enriched with bovine colostrum. Bovine colostrum is a pre-milk fluid secreted by a cow first few days after giving birth, before true milk appears. The IgCo colostrum milk is made with ingredients sourced from strong, healthy pasture-fed dairy cows from New Zealand. It is a highly nutritious functional food that not only possesses all the goodness of milk but contains immune factors, antibodies, growth factors and other health promoting substances. These substances work synergistically to help regulate our body system and keep us in good health. The IgCo Colostrum milk is in the form of pasteurized milk powder, manufactured by Altratec Sdn Bhd (GMP certified). The IgCo colostrum milk is a Halal product, as certified by Jabatan Kemajuan Islam Malaysia (JAKIM). So far, there is no known side effect for the IgCo colostrum milk.

5. What kind of study products will I receive?

If you agree to participate in the study, the doctor may need to perform some tests and examinations to determine if you are suitable for the study. If you are deemed suitable, you will be randomly assigned to one of the treatment groups below by using the SPSS software. You have equal chance of being assigned to each of the groups. Neither you nor the doctor will know which group you are assigned to but in case of emergencies, this information is available to your doctor.

Group 1: IgCo colostrum milk powder (pasteurized; Halal) – take 1 sachet (15g) each time by mixing it in a glass of lukewarm water (50ºC and below), twice daily. Do not mix the products with hot water. Consume at morning and evening, preferably before meals. If you have history of stomach problems such as gastric, please consume after meals. If you do not have any history of stomach problems, you can opt to consume before meals.

Group 2: A placebo (skim milk powder; pasteurized; Halal) – take 1 sachet (15g) each time by mixing it in a glass of lukewarm water (50ºC and below), twice daily. Do not mix the products with hot water. Consume at morning and evening, preferably before meals. If you have history of stomach problems i.e. gastric, please consume after meals. If you do not have any history of stomach problems, you can opt to consume before meals. A placebo looks like the study treatment but has no active ingredients.

6. What will happen if I decide to take part?

a) You will be required to attend a screening session where your fasting blood sample (total of 20 ml blood) and other necessary data will be collected. A measurement of your waist circumference, height, weight and BMI will also be taken. You will be informed via phone call or email if you are eligible to participate in the study (aged between 50-69 years old; without current or past history of cancer or on chemotherapeutic regiment; not allergic/intolerance to dairy products; without chronic kidney diseases/kidney failure, uncontrolled hypertension/diabetes, heart, cardiovascular disease; not pregnant or lactating).

b) A total of 2 study visits – first day of study commencement and month 3. Interventional product will be given on the first day of study commencement and fasting blood collection will be taken during the first day of study commencement and month 3. A total of 20 ml blood will be collected per visit.

c) You are advised to consume the interventional product once before breakfast and once before dinner. However, if you have history of stomach problems i.e. gastric, please consume after meals. If you do not have any history of stomach problems, you can opt to consume before meals.

d) You do not need to modify your current lifestyle as changes might affect the study outcome.

e) You do not need to stop or modify any current medications or treatments you are on. If you are unsure, please consult your medical doctor.

7. When will I receive the trial product and how should it be kept?

You will be given the study product during the first study visit and you will be required to consume it every day throughout the treatment period of the study. You must not give the product to anyone else. The study staff will instruct you on how the product must be handled and stored. Please ensure that you keep your used and partly used study products after you have finished with them. You will need to bring back all study products (partly used, unused and empty packaging material) to the study site during the last study visit.

8. What are my responsibilities when taking part in this study?

It is important that you answer all of the questions asked by the study staff honestly and completely. If your condition or circumstances change during the study, you must tell the medical doctor. It is very important that your medical doctor be informed very rapidly of any

eventual changes to your health during your participation in the study. For your own security, it is important that you follow your medical doctor's instructions throughout the entire duration of the study.

9. What are the potential risks and side effects of being in this study?

There is no known side effect of the investigational product. Minor bruising and pain might occur during or after blood withdrawal. However, if a side effect occurs during the duration of the study, please report to the medical doctor immediately and you will be referred to the nearest medical facility.

10. What are the benefits of being in this study?

There may or may not be any benefits to you for participating in this study. The supplement given may or may not help to improve your overall health and wellbeing. However, information obtained from this study will help improve the treatment or management of other patients with the same condition.

11. What if I am injured during this study?

If you are injured as a result of being in this study, you should contact the investigator and medical doctor and you will be referred to the nearest medical facility. In the event of a bodily injury or illness directly resulting from the study product or a medical procedure required for this study, the sponsor will pay for reasonable and necessary treatment. The sponsor is not responsible for medical expenses due to pre-existing medical conditions, any underlying diseases, any ongoing treatment process, your negligence or willful misconduct, the negligence or willful misconduct of your medical doctor or the study site or any third parties.

12. Who is funding the research?

This study is sponsored by SNI Sdn. Bhd. who will pay for all study products and procedures. The sponsor will financially compensate the time spent by the study staff, use of facilities, etc., for including you in the study. You will be reimbursed RM 50 for your travel expenses for each study visit (total RM 100).

13. Can the research or my participation be terminated early?

The medical doctor or the sponsor may be due to concerns for your safety, stop the study or your participation at any time. You may be discontinued from study treatment at any time if you, or the investigator, or the Sponsor feels that it is not in your best interest to continue. The following is a list of possible reasons for study treatment discontinuation:

- Subject withdrawal of consent (or assent)
- Subject is not compliant with study procedures
- Adverse event that in the opinion of the investigator would be in the best interest of the subject to discontinue study treatment
- Protocol violation requiring discontinuation of study treatment
- Lost to follow-up
- Sponsor request for early termination of study
- Pregnant (lactating)

14. Will my medical information be kept private?

All your information obtained in this study will be kept and handled in a confidential manner. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. The data from this study will be made into a report which may be published. Access to the data is only by the research team and the REC UKM. The data will be reported in a collective manner with no reference to an individual. Hence your identity will be kept confidential.

15. Who should I call if I have questions?

If you have any questions about the study or if you think you have a study related injury and you want information about treatment, please contact the principal investigator, Assoc. Prof. Dr Razinah Sharif @ Mohd Sharif at telephone number +603-9289 7259 or Dr. Ooi Theng Choon at telephone number +6012-902 9975. If you have any questions about your rights as a participant in this study, you can also contact the Research Ethics Committee (REC), UKM for clarifications.

16. Investigators' Details:

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