Participant Information Sheet/Consent Form

Central West Cancer Centre

Title	Rice Bran Arabinoxylan Compound (RBAC) and quality of life of cancer patients
Short Title	RBAC-QoL
Protocol Number	H19244
Project Sponsor	Charles Sturt University
Coordinating Principal	Dr Sokcheon Pak, Senior Lecturer, School of Biomedical Sciences, Charles Sturt University
Principal Investigator	Dr Rob Zielinski, Medical Oncologist, Orange and Bathurst Health Services
Associate Investigators	Dr Peter Micalos, Lecturer, School of Biomedical Sciences, Charles Sturt University Dr Thomas Jeffries, Lecturer, School of Science and Health, Western Sydney University Soo Liang Ooi, PhD student, School of Biomedical Sciences, Charles Sturt University
Location	Central West Cancer Centre, Orange Health Service, 1502 Forest Road, ORANGE, NSW 2800

Part 1. What does my participation involve?

1. Introduction

You are invited to take part in this research project because you have been diagnosed with cancer and you are starting your treatment at Central West Cancer Centre (this centre). The research project is measuring whether a food supplement will have an effect on the quality of life of cancer patients. The food supplement is called Rice Bran Arabinoxylan Compound or RBAC for short.

This Participant Information Sheet and Consent Form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether to take part in this research project, you might want to talk about it with a relative, a friend or your local doctor.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. The food supplement is not a treatment for your cancer. You will continue to receive the best possible care and treatments from your doctors regardless of whether you take part in this research or not.

If you decide you want to take part in the research project, you will be asked to sign the consent form. By signing it you are telling us that you:

- understand what you have read.
- consent to take part in the research project.
- consent to follow the procedures that are described.

- consent to allow us to collect, store, test, and analyse your blood and stool (optional) samples.
- consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet and Consent Form to keep.

2. What is the purpose of this research?

This research has been initiated by Dr Sokcheon Pak of Charles Sturt University (the sponsor), funded by Daiwa Pharmaceutical Co., Ltd. (Daiwa) of Japan and BioMedica Nutraceuticals Pty. Ltd. of Australia (BioMedica), and conducted by Dr Rob Zielinski who will be the study doctor at this centre and most likely the doctor who treats your cancer. The results of this research will be used by the associate investigator, Soo Liang Ooi, to obtain a Doctor of Philosophy (PhD) degree.

The aim of this study is to evaluate the effect of a food supplement on the quality of life of cancer patients. Quality of life refers to the overall functioning and well-being of a patient during cancer treatment. The significance of this study is to learn whether this specific food supplement will have any effect on the quality of life of cancer patients while they are undergoing treatment.

RBAC is derived from fermenting rice bran with the enzymes of Shiitake mushroom.
Daiwa is the manufacturer of RBAC and will supply it for our research use. The RBAC product used in this research is available for sale in Australia as a food supplement. It is marketed by BioMedica under the brand name Ribraxx.

We need to stress that RBAC is **NOT** a treatment for cancer or any other condition. All treatments such as medications, drugs and devices must be approved for use by the Australian Federal Government's Therapeutic Goods Administration. RBAC is not a listed complementary medicine on the Australian Register of Therapeutic Goods (ARTG). Hence, it is not approved to be used as a treatment or as complementary medicine for any condition in Australia. RBAC is a functional food which means that it is a food item that may or may not have a positive effect on health beyond its basic nutrition.

RBAC has been studied for its health-promoting values for close to 30 years. Through tests performed in cell samples, animals, and in humans, we know that RBAC can potentially affect the body's immune system. Specifically, in cancer patients, research has found that RBAC may potentially enhance their immune system during treatment, reduce any side-effect, make patients feel better, and improve the results of treatment. However, there are not enough human clinical trials to confirm such potential benefits. The purpose of this research is to provide the best quality evidence to fill a gap in knowledge. The findings from this research can improve the understanding on the effect of RBAC during cancer treatment, supply evidence to validate the health benefits of RBAC and potential side effects, and potentially contribute to better care for cancer patients in the future.

3. What does participation in this research involve?

You will be participating in a randomised controlled research project. Sometimes we do not know whether a food supplement is having any health effect. To find out we need to compare it with a placebo. A placebo looks like the real supplement, but it contains no active ingredients. We put people into groups and give each group either the food supplement or the placebo. The results are compared to see if one is better. Half of the participants in this project will receive the

RBAC supplement and the other half will receive the placebo. To try to make sure the groups are the same, each participant is put into a group by chance (random).

This research project has been designed to make sure that the researchers interpret the results in a fair and appropriate way and avoid study doctors or participants jumping to conclusions. The study will be a double-blind study. This means that neither you nor your study doctor will know whether you are receiving the real supplement or placebo. However, in certain circumstances, your study doctor can find out which one you are receiving.

There are no additional costs associated with participating in this research project, nor will you be paid. All laboratory tests beyond routine care, supplements, and questionnaires required as part of the research project will be provided to you free of charge.

The procedures of participation are as follows:

First session

1. To participate in this research, you must first understand what this research is about and provide us with your consent (by signing the Consent Form).

2. Once you have consented to participate in this research, the study doctor will gather information from you on your medical history and perform a physical examination (including taking your vital signs such as body temperature, respiration rate, pulse and blood pressure) as part of the process to assess whether you are eligible to participate in this project.

3. If you are eligible, we will assign you to one of the two groups. This assignment process is random and is done using a computer program. You will not be informed which group you are being assigned to.

4. We will then provide you with a Quality of Life (QoL) questionnaire. The questionnaire has 30 questions which will tell us about you and your health. It will take 9 minutes on average to complete. Please answer all the questions yourself by circling the number that best applies to you. There are no 'right' or 'wrong' answers to these questions.

5. Since there are other factors which may affect your QoL during cancer treatment, we will also provide you with additional questionnaires to complete. These questionnaires are optional to the study. You can choose not to complete them. However, you will need to make the choice at the time of providing consent.

    a. [Optional] We will also provide you with an International Physical Activity Questionnaire (IPAQ). This questionnaire has seven questions which will tell us about your level of physical activities over the last seven days. It will take about five minutes to complete this questionnaire.

    b. [Optional] To understand the type of complementary therapies that you may also use over the last 3 months, we will also need you to fill in a questionnaire on complementary therapies use (CAMQ). This questionnaire has 16 questions, and it takes less than 10 minutes to complete.

c. [Optional] We also want to know about your eating habits. We will require you to complete an online food frequency questionnaire (FFQ) of the Australian Eating Survey ® (AES). The survey will ask you how often you eat a list of 120 commonly consumed foods and 15 behavioural questions. It takes just 15 minutes to complete an online survey.

6. We will provide you with a pack of food supplement. Within it, you will find a total of 126 sachets containing either RBAC or placebo in dry powder form. You need to take the powder every day. Take 2 sachets in the morning after your breakfast and another sachet in the evening after dinner. To make the dry powder easy to swallow, open the sachet(s) into half a glass of water. Stir completely and drink it right away. If you forget to take the supplement once, say in the morning, you can take all 3 sachets together in the evening after meal. Similarly, if you miss it in the evening, you can take all 3 sachets in the morning. If you are asked to abstain from eating any food before your cancer treatment, you need to stop taking this food supplement as well. You can continue taking this supplement after you resume eating.

7. You will be given a blood sample collection request form to take to Barratt & Smith Pathology (257 Anson St, Orange NSW 2800) for your blood samples to be collected immediately after the first visit and one to three days before the next follow-up session.

8. [Optional] You will be given a stool sample collection kit and detailed instructions on how to properly take a swab of your stool at home. You will collect a stool sample immediately after the first visit and during one to three days before the next follow-up session. You will hand over the collected sample to the staff during your visit for blood sample collection. Stool sample collection is also optional to this study. You can choose not to provide your stool sample. Similarly, you will need to make the choice at the time of providing consent.

9. You will also be asked to stand on the weight machine for us to record your body weight, body fat percentage, and muscle mass. We will also measure your standing height.

10. We will also access your medical files stored in the cancer centre's computer system to collect information, such as diagnosis and routine blood test results, which have already been collected during your medical examination.
11. We will confirm your next follow-up session with you, which will be approximately 6 weeks later.

Follow-up sessions

1. <u>If you choose to provide your stool sample</u>, about one to three days before every follow-up session, you will take a sample of your stool with the collection kit provided.

2. You will then visit Barratt & Smith Pathology to have your blood samples collected and hand over the collected stool sample (if any).

3. You will complete a new QoL questionnaire at every follow-up session. Your answers will help us to understand any changes in your health and your physical activity levels.

You do not need to remember your previous answers, just answer each question as it relates to you now.

4. If you choose to complete the additional questionnaires, you will also complete a new IPAQ at every follow-up session. During your second and also the last follow-up session, you complete a new CAMQ. At the final follow-up session, you will also complete the online AES questionnaire again to allow us to find out any changes in your dietary habit over the last 24 weeks.

5. Your body weight, body fat percentage, and muscle mass will also be taken at every follow-up session for us to track the changes over time.

6. You must bring back the supplement pack given to you with any remaining unconsumed packets. We will do a packet count to track the total number of packets used.

7. You will be given a new supplement pack and be reminded of how to take the supplement at every follow-up session.

You will be involved in the research for a duration of 24 weeks with a total of 4 follow-up sessions that are 6-weekly apart.

4. What do I have to do?

By participating in this research, we require you to commit to:

1. take 3 packs of the food supplement daily for 24 weeks according to the instructions given.

2. attend follow-up sessions to complete a QoL questionnaire every 6 weeks and complete all IPAQ, CAMQ, and AES questionnaires at the required time points, if you agreed to complete these additional questionnaires.

3. take a swab of your stool sample with the collection kit provided before every session, if you choose to provide your stool sample.

4. visit Barratt & Smith Pathology for blood sample collection and handing over the collected stool sample (if any), one to three days before every session.

5. allow us to store, test, and analyse your stool (if any) and blood samples collected.

You will still be undergoing your cancer treatment while participating in this research. You should follow any advice given by your cancer treatment doctor on what you should or should not do. Your cancer treatment doctor will also advise you on the medication that you need to take and what medication you should not take.

You must avoid taking any additional food supplement, including nutritional (e.g. vitamins, minerals, probiotics) or herbal, except those prescribed by your study doctor. If you are taking any other food supplement regularly, you must stop taking them during this study.

5. Other relevant information about the research project

We aim to recruit 50 participants for this project. Depending on how fast we can recruit the participants, this project will run for about one and a half to two years. This project will be conducted at a multiple study sites. The research is conducted by a team of researchers from CSU in collaboration with Dr Rob Zielinski. Before starting this research, the team from CSU has completed a comprehensive literature review of the available evidence on how RBAC can complement cancer treatment.

The stool sample collection kits used in this study are commercially purchased from Microba. The use of this kit is not the standard of care for your treatment. The kit is not classified as a therapeutic good according to the Therapeutic Goods Act (1989). Therefore, it is not listed on the ARTG. The swab is a non-diagnostic device which is not used for preventing, diagnosing, curing or alleviating any disease, ailment, defect or injury. The kit is a research-only device and will not be used for any other purpose in this study. Microba has no role in this study and the company will not have access to the stool samples collected in this study. No study data will be provided to Microba.

The AES is developed and administered by the University of Newcastle. The AES is used only as a food frequency questionnaire (FFQ) in this study to detect any changes in your eating habits at the start and the end of the study. We purchase the rights to use the AES through a commercial arrangement, and the University of Newcastle is not involved in the study. However, the University of Newcastle can have access to the data you complete on this online service, even though the University of Newcastle will not use the data. The FFQ data is only identifiable with unique participant identifiers with no personal information. Completion of the AES is also not part of the standard of care for your treatment.

6. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information Sheet and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Central West Cancer Centre.

7. What are the alternatives to participation?

You do not have to take part in this research project to receive cancer treatment at this centre. RBAC is **NOT** a part of your cancer treatment, hence you will continue to receive all the standard treatment and care even if you are not participating in this research.

You do not have to take part in this research project to obtain RBAC for your own use. RBAC is available as a commercial food supplement with the product name Ribraxx. You may contact

any nutritionists or complementary health practitioners who are authorised resellers of Ribraxx.

8. What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research, however, possible benefits may include lesser side-effects during cancer treatment, better quality of life, and stronger immune system. These benefits may or may not help you during your cancer treatment.

9. What are the possible risks and disadvantages of taking part?

RBAC is a food supplement made from rice bran. There are no known side-effects that are directly caused by taking RBAC. However, in clinical trials, participants may sometimes experience unexpected side-effects; even to placebo treatments. As you will be undergoing your cancer treatment while taking part in this project, there may also be some side-effects due to the interaction between RBAC and the cancer treatment you receive, which is currently unknown to the researchers. We cannot guarantee you that RBAC will not interact with your cancer treatment, even though current research tells us that this is highly unlikely.

Your cancer treatment doctor should have already provided you with all the possible side-effects of the cancer treatment you receive. You may have none, some or all of the side-effects, and they may be mild, moderate or severe. If you have any of the side-effects or are worried about them, talk with your cancer treatment doctor. Your cancer treatment doctor will also be looking out for side-effects. There may be side-effects that the researchers do not expect or do not know about. Tell your cancer treatment doctor immediately about any new or unusual symptoms that you get.

Many side-effects go away shortly after treatment ends. However, sometimes side-effects can be serious, long-lasting or permanent. If a severe side-effect or reaction occurs, your doctor may need to stop your cancer treatment and/or the taking of this food supplement. Your cancer treatment doctor will discuss the best way of managing any side-effects with you.

10. What will happen to my test samples?

By participating in this research, you agree to allow us to collect, store, test, and analyse your blood samples. The collection of these samples is a mandatory component of this project as it allows the study doctor to monitor your condition for both routine care and for our research purposes to evaluate any potential changes to your immune system while taking the supplement.

All collection of blood samples will be done at Barratt & Smith Pathology. We will collect about 10-20 ml of your blood sample during every visit. One portion of the blood samples collected will be immediately used in routine blood tests required by your study doctor to review your treatment and condition. After testing, this portion will be destroyed by placing in the human clinical waste for disposal in accordance with physical containment two (PC2) laboratory regulations. The routine blood test results will also be used in this research.

Another portion will be prepared by Barratt & Smith Pathology into blood serum (about 0.6 ml of serum in 2 tubes). The blood serum containers will be individually coded with your assigned number, your initials, and the date of collection. To protect your privacy, no personal information

will appear on the blood serum containers. These containers will then be sent to Charles Sturt University for temporary storage at -80°C for not more than one year. The stored blood serum will then be transported in batches to a specialised laboratory (Eve Technologies Corp) in Canada for a detailed analysis of the biomarkers of your immune system. All transportation of samples will be done by a specialist company capable of handling biospecimens in accordance with the governing regulation (Biological Substances Cat B UN 3373). The blood serum will be tested and analysed immediately after receipt. Upon completion, the blood serum will be placed in human clinical waste for disposal and destroyed following the local laboratory regulations (the Canadian Biosafety Standards and Guidelines).

If you agree to allow us to collect, store, test, and analyse your stool samples, only a small amount (about 50 – 300 mg) of stool is collected using the stool collection swab. The collected sample should be kept in the container provided with the lid tightly closed and properly sealed with the safety envelop slip. This container is filled with a drying agent that stabilises the stool sample for up to four weeks at room temperature. Therefore, you do not need to put the collected sample in the refrigerator. Once you handed in the collected sample at Barratt & Smith Pathology, it will be sent to Charles Sturt University for temporary storage at -80°C for not more than one year. The stored stool sample will be transported in batches to the Western Sydney University's (WSU) microbiology laboratory for the analysis of the composition of your gut microbes.

All collected samples are to be used specifically for this research only. We will not collect and store your samples more than the amount required for this research and will not use the samples for any related or future research. We will not conduct any genetic testing on the collected blood samples. We will perform genomic testing on the collected stool samples to understand the composition of bacteria in your gut.

If additional samples or tissue are needed in the course of the research, you will be asked to provide additional consent for their collection.

11. What if new information arises during this research project?

Sometimes in the course of a research project, new information becomes available about the RBAC. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, you may do so, and it will not affect your cancer treatment. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, your study doctor will explain the reasons.

12. Can I have other treatments or complementary therapies during this research project?

While you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for other conditions or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies,

acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

13. What if I withdraw from this research project?

If you decide to withdraw from the project, please notify the study doctor or the study staff before you withdraw. This notice will allow that person to make arrangement for your withdrawal.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional information from you, although information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with the law. You should be aware that data collected up to the time you withdraw will form part of the research project results. Additionally, all the samples already collected and stored will still be used in testing and analysis of results in this research. If you do not want the researchers to do this, you must tell them before you join the research project.

14. Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The food supplement has been shown not to be effective
- The food supplement has been shown to be effective and there is no need for further testing
- Decisions made in the commercial interests of the company which funds this project or by local regulatory/health authorities.

15. What happens when the research project ends?

You will continue to be cared for by your doctor at this centre after you have completed all the requirements of this research project.

We will keep you informed when the research project is completed, and we will send you a summary of the results.

Part 2. How is the research project being conducted?

16. What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your case file will be kept securely at this centre in a locked cabinet. Access to your case file is restricted only to the study doctor and relevant research staff. All your study records are identified by code number only. Any records that contain your names or other personal

identifiers, such as the signed informed consent forms, will be stored separately from your case file. Any digital records of your information that are stored in databases and computer systems will also be secured with password-protected access system.

The research data collected will be stored securely at the Research Data Storage of Charles Sturt University and will be managed with the established Research Data Management Guidelines. The access to the data is restricted to the research team only. The research data will be retained for 15 years after the completion of the research project.

Your information will be used mainly for the purpose of this research project. However, for the good of scientific research, the data may also be shared for reuse in other related research or new research in the future. All sharable data will be provided in such a way that you cannot be identified, except with your permission.

Information about you may be obtained from your health records held at this centre and other health services for the purpose of this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of Charles Sturt University, Central West Cancer Centre, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

In accordance with relevant Australian and/or New South Wales privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project and for the future research that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

17. Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

18. Who is organising and funding the research?

This research is organised by Dr Sokcheon Pak and sponsored by Charles Sturt University.

The research is being funded by Daiwa, the manufacturer of the products, and BioMedica, the sole distributor of the RBAC products in Australia.

By taking part in this research project you agree that data generated from analysis of these materials may be provided to Daiwa and BioMedica. We will not disclose your personal information. The funding companies may directly or indirectly benefit financially from knowledge acquired through analysis of your samples. In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Charles Sturt University or the research team or the study doctors, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

19. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC - CRGH of the Sydney Local Health District and Charles Sturt University HREC. If you have any concerns or complaints about the conduct of the research study, you may contact the Executive Officer of the Ethics Committee on (02) 9767 5622.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

20. Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side-effects), you can contact the principal study doctor:

Clinical contact person

Name	Dr Rob Zielinski
Position	Medical Oncologist, Orange and Bathurst Health Services
Telephone	(02) 6369 3380 (02) 6369 3000 [Orange Hospital - for after-hour concerns]
Email	Rob.Zielinski@health.nsw.gov.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	[Name of Site Complaint Person]
Position	[Site Complaint Person Position]
Telephone	[Site Complaint Phone]
Email	[Site Complaint Email]

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Human Research Ethics Committee - CRGH of the Sydney Local Health District.
HREC Executive Officer	Kate Flinders
Telephone	(02) 9767 5622
Email	Kate.Flinders@health.nsw.gov.au

Local HREC Office contact (Single Site - Research Governance Officer)

Name	Phil Sanders
Position	Research Governance Officer
Telephone	(02) 6330 5948
Email	Anthony.Sanders@health.nsw.gov.au

Consent Form - *Adult providing own consent*

Title	Rice Bran Arabinoxylan Compound (RBAC) and quality of life of cancer patients
Short Title	RBAC-QoL
Protocol Number	H19244
Project Sponsor	Charles Sturt University
Coordinating Principal Investigator	Dr Sokcheon Pak, Senior Lecturer, School of Biomedical Sciences, Charles Sturt University
Principal Investigator	Dr Rob Zielinski, Medical Oncologist, Orange and Bathurst Health Services
Associate Investigators	Dr Peter Micalos, Lecturer, School of Biomedical Sciences, Charles Sturt University Dr Thomas Jeffries, Lecturer, School of Science and Health, Western Sydney University Soo Liang Ooi, PhD student, School of Biomedical Sciences
Location	Central West Cancer Centre, Orange Health Service, 1502 Forest Road, ORANGE, NSW 2800

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Charles Sturt University concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I consent to the storage and use of blood samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for this specific research project.

For the optional study components [#]:

I consent / do not consent to complete additional questionnaires for the collection of information on my physical activities, dietary habits, and use of complementary therapies during the study as described in the relevant section of the Participant Information Sheet, for this specific research project.

I consent / do not consent to the storage and use of stool samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for this specific research project.

[#] Please strike out and initial whichever option does not apply to you.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Trial Coordinator

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/ Trial Coordinator (please print) _____

Signature _____ Date _____

Note: All parties signing the consent section must date their own signature.