Participant Information and Consent Form

Title:	*ANTIC STUDY: **A** **N**utrition **T**rial **I**n **C**OPD* A phase 2, prospective, randomised, open, blinded end-point (PROBE), controlled, cross-over, multi-centre, nutritional interventional study in chronic obstructive pulmonary disease (COPD)
Protocol number:	CTC400
Study Sponsor:	The University of Sydney
Coordinating Centre:	NHMRC Clinical Trials Centre
Principal Investigator:	Professor Lisa Wood
Associate Investigator(s):	Dr Bronwyn Berthon and Dr Kurtis Budden
Site:	Hunter Medical Research Institute (HMRI), The University of Newcastle

1. Would you like to take part in this clinical study?

You are invited to take part in this clinical research study called the ANTIC Study. This is because you have Chronic Obstructive Pulmonary Disease (COPD). This document tells you about the study and describes what will happen if you take part.

Please read this document carefully. If there is anything that you don't understand or want to know more about, please ask us. Participation is voluntary. Before deciding whether to take part, you might want to talk to a relative, friend or your local doctor.

If you decide to take part in the study, we will ask you to sign the consent form (near the end of this document). You may opt to receive the Participant Information and Consent Form by email and sign the consent form electronically. This is commonly known as e-consent. You will be given a copy to keep.

2. What is the purpose of this study?

Inflammation is an important part of your body's healing process. People with COPD often have inflammation, which can cause damage to the lungs. The purpose of this study is to determine whether dietary fibre supplementation is effective in reducing inflammation in people with COPD.

The microbiome is a collection of microscopic organisms, such as bacteria, that naturally live on and inside the human body. Although they are very small, together they contribute in a big way to human health and wellness. Promising evidence shows a link between the gut and lung microbiomes. It has been suggested that using diet to improve 'gut health' by addressing the microbiome imbalances in the gut may then decrease lung inflammation and improve COPD symptoms.

Dietary fibres are of particular interest, two of these fibres are **inulin** and **high-amylose maize starch (HAMS)**.

This study will investigate whether the nutritional supplements, **inulin** and **HAMS** are effective in reducing inflammation in COPD. We will also investigate if there are any improvements to how your lungs work and the number of exacerbations (flair-ups) you have.

We plan to enrol 120 participants in the study in Australia.

3. Do I have to take part in this research study?

Taking part in any study is voluntary. If you don't wish to take part, you don't have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage. If you choose not to take part, or if you choose to take part and then later withdraw, you will still be able to access your routine treatment. Your choice will not affect your current or future medical care in any way.

4. What does participation in this research involve?

Consent & Screening

If you agree to participate in this study, you will be asked to sign the Participant Consent Form. Once signed, the study team will first check in more detail whether the study is suitable for you.

You will be in the study for 20 weeks (5 months). The study team may inform your local doctor of your participation in this study. Please advise the study team if you do not wish this to occur. If you agree to participate in this study, you agree to be responsible for taking the nutritional supplement according to our instructions. You also agree to follow the instructions in this document and instructions provided by the study team. If you cannot, or do not wish to accept this responsibility, please advise the study team.

Baseline Visit

Where possible, most of the baseline information will be collected from you over the telephone during your screening phone call.

At the baseline visit, the following information will be collected or procedures performed:

1. Medical history (e.g. COPD, medication use).
2. Demographics (e.g. age, gender, ethnicity, height, weight).
3. Lung testing - If you have not had a lung function test within the past 3 months, you will undergo testing which will include spirometry. Spirometry involves blowing into a machine to measure how much air your lungs can hold and how quickly you can exhale. The tests are safe and painless and will be conducted by your study doctor or specialist technicians.
4. Details of blood results from routine testing.
5. Short questionnaires to assess your COPD symptoms, how you are feeling, and the fibre you are consuming in your regular diet.
6. A blood sample will be collected.
7. Two urine samples will be collected. Instructions on how to collect and store your urine will be provided by your study team.
8. Stool sample (poo) and an oral (mouth) swab will need to be collected at home and sent to the Microbiome Research Centre within 48 hours of collection. Instructions on how to collect these samples will be provided to you, as well as a pre-paid post pack to send the samples.

This visit may take approximately 3 hours of your time. All of the baseline procedures must be completed before you can be 'randomised' (like rolling a dice) to receive study treatments in a specific order.

Treatment Order (Randomisation)

We do not know in which order you will receive the study treatments, until you start the study and are 'randomised' to a treatment order. This is the order that you will receive the treatments while on the study. This study is an open label study. This means the study doctor and you will know which treatment you are receiving and in what order.

Study Treatments

Inulin and **HAMS** are fibres that come from plants. Inulin comes from chicory roots. HAMS is a starch that comes from corn. Both inulin and HAMS have not yet been investigated as a treatment for COPD and we do not know if these treatments will work for you. Therefore, there are experimental treatments for COPD. Both inulin and HAMS have however been studied in many other inflammatory disorders without major side effects.

You will be in the study for 20 weeks (5 months) in total. During the study you will receive each active treatment for a 4-week period.

- Control treatment period 1: During the control treatment period you will continue to receive standard medical care and be encouraged to continue your regular diet.
- Treatment period 2 (inulin): You will be advised to take 6g inulin powder twice a day (12g total per day) mixed with water and taken with food, or you can mix with any of your usual food or meals.
- Treatment period 3 (HAMS): You will be advised to take 10g HAMS powder twice a day (20g total per day) mixed with water and taken with food, or you can mix with any of your usual food or meals.

Following each period, you will have a 4-week 'washout' period. During the washout period you will not be receiving any treatment. This period is important as it allows for better comparison of the effect of the active treatments (inulin and HAMS) on your body.

Additionally, you will be asked to maintain your regular diet for the entire 20-week treatment period.

Clinic Visits

You will need to attend clinic visits at The Hunter Medical Research Institute (HMRI). Location details will be provided by your study team.

Clinic visits will occur at Week 0 and before and after each treatment period (Week 4, Week 8, Week 12, Week 16 and Week 20). You will need to attend in person for these clinic visits. You should allow up to 3 hours for the first visit and then 2 hours for subsequent visits. There will be 6 visits to the HMRI clinic in total.

Prior to each clinic visit, the following will be required:

1. Stool sample (poo) and an oral (mouth) swab will need to be collected at home and sent to the Microbiome Research Centre within 48 hours of collection. Instructions on how to collect these samples will be provided to you, as well as a pre-paid post pack to send the samples.
2. Two urine samples will need to be collected the day before and the morning of your clinic visit. Instructions on how to collect and store your urine will be provided by your study team. Both samples are to be brought into the clinic visit.

Each clinic visit at Weeks 4, 8, 12, 16 and 20 will involve:

3. Short questionnaires to assess your COPD symptoms, how you are feeling, and any symptoms you are experiencing that may be related to the treatment.
4. Details of your symptoms and current smoking status.
5. Details of your current medications.
6. Treatment (inulin, HAMS or control) will be provided to you at Week 0, Week 8 and Week 16.
7. A diary will be provided to you at Week 0 and reviewed at Week 4, Week 12 and Week 20 to monitor study treatment compliance.
8. Review of any unused study treatment to monitor study treatment compliance.

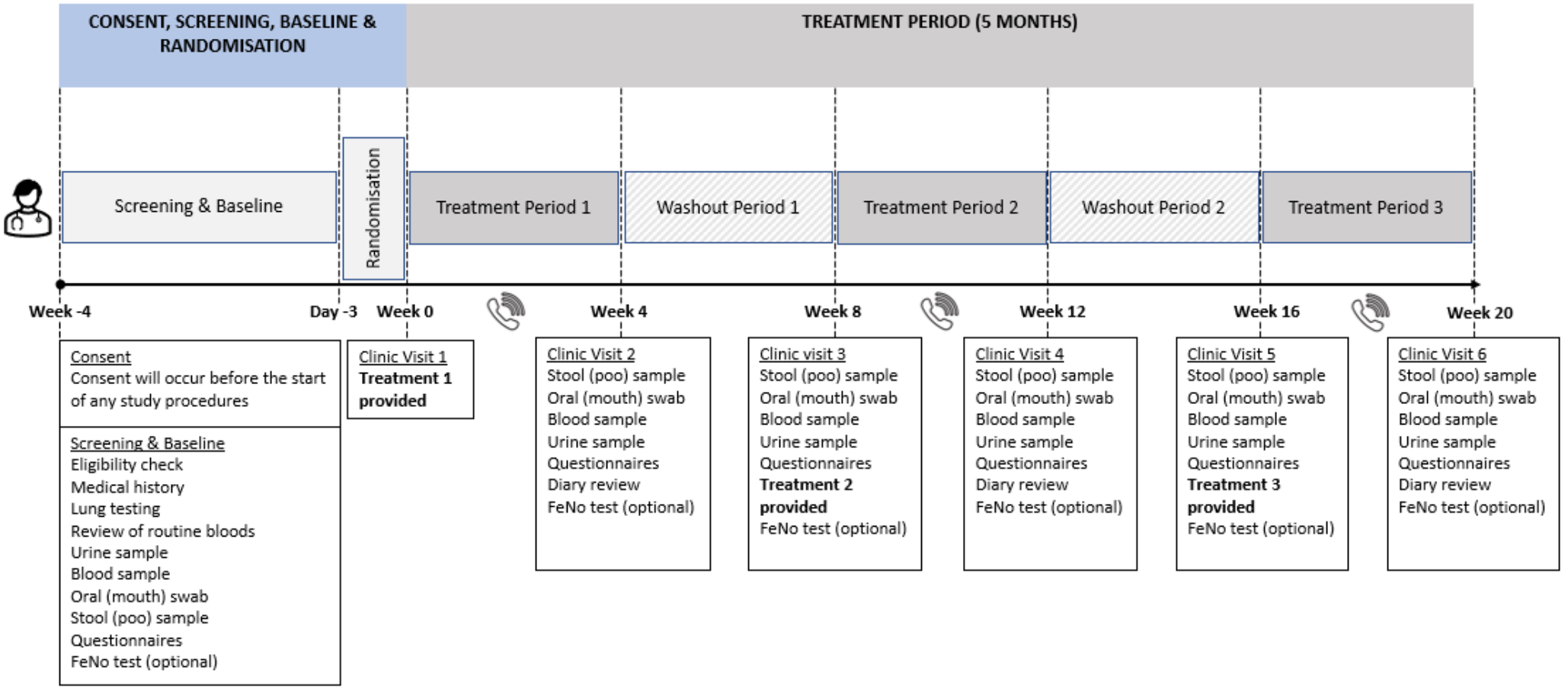
If your site is participating in the optional fractional exhaled nitric oxide (FeNO) test, this test will also be performed at all clinical visits, pre and post each intervention period. It measures the amount of nitric oxide in your breath to indicate the level of inflammation in your airways.

Phone Calls

A member of the study team will ring you to ask about the study treatment and any symptoms you may be experiencing at Week 2, Week 10 and Week 18.

Infographic

The infographic below shows the timeline and study procedures that will take place during each treatment period whilst you are on the study, which have been described above.


CONSENT, SCREENING, BASELINE & RANDOMISATION
TREATMENT PERIOD (5 MONTHS)
Screening & Baseline
Randomisation
Treatment Period 1
Washout Period 1
Treatment Period 2
Washout Period 2
Treatment Period 3
Week -4
Day -3
Week 0
Week 4
Week 8
Week 12
Week 16
Week 20
Consent
Consent will occur before the start of any study procedures
Screening & Baseline
Eligibility check
Medical history
Lung testing
Review of routine bloods
Urine sample
Blood sample
Oral (mouth) swab
Stool (poo) sample
Questionnaires
FeNo test (optional)
Clinic Visit 1
Treatment 1 provided
Clinic Visit 2
Stool (poo) sample
Oral (mouth) swab
Blood sample
Urine sample
Questionnaires
Diary review
FeNo test (optional)
Clinic visit 3
Stool (poo) sample
Oral (mouth) swab
Blood sample
Urine sample
Questionnaires
Treatment 2 provided
FeNo test (optional)
Clinic Visit 4
Stool (poo) sample
Oral (mouth) swab
Blood sample
Urine sample
Questionnaires
Diary review
FeNo test (optional)
Clinic Visit 5
Stool (poo) sample
Oral (mouth) swab
Blood sample
Urine sample
Questionnaires
Treatment 3 provided
FeNo test (optional)
Clinic Visit 6
Stool (poo) sample
Oral (mouth) swab
Blood sample
Urine sample
Questionnaires
Diary review
FeNo test (optional)

Other study activities

If you are attending a participating site, you may be asked to participate in a companion study that will be conducted by researchers at Hunter Medical Research Institute/University of Newcastle. In addition to the above study assessments, participants at this site will be asked to donate sputum samples. Additional information and consent forms will be provided to participants who are eligible for the companion study.

Other treatments or medication

It is important to maintain your usual diet for the entire 20-week study duration.

During the study, you should not take any fibre-based supplements (e.g. Metamucil, Benefibre). If you are currently taking a fibre-based supplement, you will be required to cease this for a least 4 weeks prior to commencing the study and until the study ends.

You will be asked about any treatments or medications that you are taking, including non-prescription medicines, vitamins or herbal remedies and any changes during the study.

Study cost

There is no additional cost associated with taking part in this study, nor will you be paid. All study-related treatments, medication and tests will be provided at no cost to you. You should ask the study doctor to explain any payments for which you may be responsible. Your study team will be able to advise you of transport options available in your area but the study is not able to reimburse any transport costs.

5. What are the alternatives to taking part?

If you do not take part in the study, you will continue to receive routine clinical care. If you do not wish to consent to the study, you will continue to receive usual care through respiratory, general practitioners and other medical teams.

6. What are the possible benefits of taking part?

We cannot guarantee that you will receive any benefits from this study. The results of this study may help patients with COPD in the future, however there may be no clear benefit to you from your participation in this study.

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

Your study doctor or members of the study team will discuss the risks and inconveniences.

Dietary fibre is a nutrient contained in many of the foods you eat. When you increase your fibre intake some people experience mild gastrointestinal symptoms such as bloating and increased flatulence. If you have any of these side effects, or are worried about them, talk with your study team. Your study team will be monitoring you for side effects.

There may also be side effects that the researchers do not expect or do not know about and that may be important. Tell your study doctor immediately about any new or unusual symptoms. Your study doctor will discuss the best way of managing any side effects with you.

Risks of study tests

Blood test: You may get bruising where the needle enters your skin, get dizzy or faint. Having a blood sample taken may cause you some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated. Please tell us if you normally feel dizzy or faint when you have blood collected.

8. What will happen to my test samples?

Required research

Blood, oral swab, urine, and stool/poo samples taken before and after each treatment period will be analysed for the study. The aim of these studies is to learn more about how these study treatments affect your 'gut health' (microbiome), markers of inflammation in your blood, and other markers of disease.

Sample Identification and Storage

All samples will be labelled with a unique study number and stored securely. Only laboratory researchers involved in the study will have access to your samples and will not be able to link your samples to your personal information.

The samples will be stored until analysis at one or more of our central laboratories. Urine and blood samples will be located at The University of Sydney and stool and swab samples will be located at the University of New South Wales Microbiome Research Centre. You will retain the right to have your samples destroyed at any time by contacting your study team. If you decide to have your samples destroyed, any data or analyses that were done before the request cannot be removed. However, no additional analysis will be done on your samples, and all your remaining samples will be destroyed. The University of Sydney and University of New South Wales is responsible for organising the destruction of the samples at your request.

Future Unspecified Research (Optional)

The researchers doing this study are interested in doing additional research in the future on the blood and urine samples collected from you to better understand the nature of COPD and these treatments. If you agree, your samples will be stored for future research. Any future use would be approved by The University of Sydney and an appropriate Human Research Ethics Committee. You can indicate your wish to take part in this additional research, and have your samples stored ('banked') at the University of Sydney. The future research would not involve genetic testing.

Your samples will never be sold. You will not benefit financially if this research leads to development of a new treatment or medical tests.

Your individual results

All the laboratory research studies are experimental, and the results will not be suitable for guiding decisions about your treatment. Accordingly, your individual laboratory results will not be made available to you or your study team. You can receive feedback based on the dietary survey you complete once you have completed the study, if you wish. At the end of the entire study, a summary of the results will be provided to your study team who can discuss them with you.

9. What if new information comes up during this study?

If new information on the study interventions becomes available during this study, your study team will discuss with you what it means and whether it may affect your decision to continue in the study. If you decide to continue in the study, we may ask you to sign an updated consent form.

On receiving new information, your study team might also consider it to be in your best interests to withdraw you from the research project. If this happens, they will explain the reasons and arrange for your regular health care to continue.

10. What if I withdraw from this study?

If you decide you do not wish to continue with any aspect of this study at any time, please call the study team to discuss your decision. Your study team will discuss how to manage any health risks and provide recommendations for your ongoing care. If you choose to withdraw from taking the treatments, you can

still continue with undergoing study assessments, with this information still being valuable to the research study.

If you decide to withdraw your consent from the study by declining all study treatment and follow-up, no further study related contact or information collection will occur. You will be asked to provide a reason for withdrawal and to complete the Withdrawal from Participation form.
If you choose to withdraw from the study verbally (over the phone), the Study team/Senior Researcher will complete the Withdrawal from Participation form on your behalf and record the date and time of withdrawal. A copy of the completed withdrawal from will be provided to you.

If you withdraw your consent, information already collected for the study will be kept to ensure that the results of the study can be measured properly and will form part of the study results.

11. Could this study be stopped early?

In the unlikely event the study is stopped early, the study team will contact you to explain the reason for the decision and provide instructions for completing your study participation. This study may be stopped early for a variety of reasons including:

- Unacceptable side effects
- Decisions made by local health authorities, the study sponsor or the manufacturer of treatments used in this study.

12. What happens when the study ends?

A decision about the best ongoing treatment for you should be made between you and your doctor at that time. A summary of the study results can be obtained for you at the end of the study if you wish.

13. What will happen to the information collected about me?

Information about you may be obtained from your health records held at this site and other health services for the purpose of this study. By signing the Consent Form you agree to the study team accessing health records, collecting, and using personal and health information about you for the study. Information about your participation in this study may be recorded in your health records. Any information obtained for this study that can identify you will be treated as confidential and will only be disclosed with your permission, except as required by law.

All data and records linked with your participation in the study will only be accessed by approved study personnel. The information collected in the study database will be identified by a code number. No identifying information will leave your site. The deidentified data will be stored by the NHMRC Clinical Trials Centre in a secure study database in Sydney, Australia.

The main clinical database will be a separate database and there will be no links to the e-consent database. Only the site study team will have access to the information supplied at the time of consent. The study team at the University of Sydney will not have access to see the participant identifiable data.

The Australian Eating Survey Online (AES) - Information is only accessed by authorised personnel using secure logins and passwords. The AES data will be stored securely in Australia. Site staff will manage the link to the AES survey to you via a survey access code or QR code. The study team at the University of Sydney will not have access to see any identifiable data.

Some of the deidentified data collected for the study will be shared with study researchers including those at University of New South Wales Microbiome Research Centre in order for them to complete the analyses of your samples. Similarly, some data collected for the study will be shared with the team of researchers at Hunter Medical Research Institute/University of Newcastle for participants who will be participating in the additional companion study. None of the researchers at the University of Sydney or

University of New South Wales, will have access to any information that identifies you. Your study data will be held in paper and electronic format at site and electronically by the NHMRC Clinical Trials Centre. Electronic data will be held securely and processed on protected computers. The study data will be kept for at least 15 years from the end of the study, after which it will be destroyed in a secure manner.

In accordance with relevant Australian and State privacy and other relevant laws, you have the right to request access to your information collected and stored by the study 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 form if you would like to access your information.

Your health records and any information obtained during the study are subject to inspection and monitoring, both remotely and at the location where it is held (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the University of Sydney and NHMRC Clinical Trials Centre, the Australian Therapeutic Goods Administration and other relevant regulatory authorities, the approving Human Research Ethics Committee (HREC) and The University of Newcastle, 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.

14. Will the results of the study be published?

Once the results of the whole study are known, the results of this study will be published in a journal/s and/or presented at meetings. A summary of the results will be provided to your study doctor to discuss with you. A summary of the results will also be published on the NHMRC Clinical Trials Centre website (www.ctc.usyd.edu.au). All information provided to the public will be presented in such a way that you cannot be identified.

15. Who is conducting and funding this study?

This study is being coordinated by the NHMRC Clinical Trials Centre (CTC) and sponsored by The University of Sydney. The University of Sydney is collaborating with researchers from The University of NSW Microbiome Research Centre who will be responsible for the microbiome analysis of oral swab and stool samples. The University of Sydney is also collaborating with researchers from the University of Newcastle who will be conducting the companion study.

This study is an investigator-initiated clinical research project. This means that it is led by clinician researchers not a commercial company.

The study is being funded through the Australian Government's NHMRC Synergy Grant. The University of Newcastle will receive a payment from the CTC for undertaking this study.

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

16. Who has reviewed this study?

This project will be carried out according to the National Statement on Ethical Conduct in Human Research *(2007, updated 2023 and as amended from time to time)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

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 St Vincent's Hospital Sydney HREC.

17. What do I do if I need to seek compensation for injury?

Dietary supplements are regarded as safe. In the remote chance, you suffer any injuries or complications as a result of this study, you should contact the study team as soon as possible and you will be assisted with arranging suitable 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.

You do not give up any legal right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by treatments or equipment, or by the negligence of one of the parties involved in the study.

18. Who do I contact if I have a question or complaint?

The person you may need to contact will depend on the nature of your query.
If you want any further information concerning this study or if you have any medical problems which may be related to your involvement in the study (for example, any side effects), you can contact the study team:

Name	Position	Phone number	Email Address
Dr Bronwyn Berthon	Study Coordinator	02 4042 0116	Bronwyn.Berthon@Newcastle.edu.au
Dr Kurtis Budden	Study Researcher	02 4042 0818	Kurtis.Budden@Newcastle.edu.au
Prof Lisa Wood	Chief Investigator	02 4921 7485	Lisa Wood@Newcastle.edu.au

If you wish to discuss the study with someone not directly involved, particularly about policies, information, your rights as a participant, or if you would like to make a complaint about the conduct of the study or the research personnel managing your care, you may contact:

Reviewing HREC approving this research
This study has been approved by the St Vincents Hospital Sydney Human Research Ethics Committee (SVHS HREC). Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on (02) 8382 4960, or email SVHS.research@SVHA.org.au and quote 2024/ETH01386.

Local HREC/RGO Office approving this research
The conduct of this research has been authorised by the Hunter New England Local Health District to take place at the John Hunter Hospital site. Contact the HNE Research Office, Hunter New England Local Health District, Level 3, POD, HMRI, Lot 1 Kookaburra Circuit, New Lambton Heights NSW 2305. Telephone: 0249214140. Email: HNELHD-ResearchOffice@health.nsw.gov.au, and quote 2024/STE04706.

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Participant Consent Form

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Study Sponsor:	The University of Sydney
Coordinating Centre:	NHMRC Clinical Trials Centre
Principal Investigator:	Professor Lisa Wood
Associate Investigator(s):	Dr Bronwyn Berthon and Dr Kurtis Budden
Site:	Hunter Medical Research Institute (HMRI), The University of Newcastle

Declaration by Participant

- I have read, or someone has read to me, and I understand the Participant Information and Consent Form.
- I understand the purposes, procedures and risks of the study described in the Participant Information Sheet.
- I give permission for the study team, other health professionals, hospitals, or laboratories outside this hospital to release information concerning my medical history, disease and treatment for the purposes of this study. I understand that such information will remain confidential.
- I consent to my treating doctor/s being notified of my participation in this study and any clinically relevant information noted by the study doctor in the conduct of the study.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to take part in this study as described and understand that I am free to withdraw at any time during the study without affecting my future health care.
- I understand that I will be given a signed copy of this document to keep.
- I consent to the storage and use of my blood, urine, stool and oral swab samples taken from me during the study as described in the relevant section of the Participant Information Sheet and/or about future unspecified research.
    - this specific study
    - other research that is closely related to this study.
- I understand that some data collected for the study will be shared with researchers at the University of New South Wales Microbiome Research Centre.
- I understand that, if I consent to participate in the companion study run by The University of Newcastle, some data collected for the ANTIC study will be shared with researchers at The University of Newcastle.

Future Unspecified Research (optional)

I consent to the storage and use of blood and urine samples taken from me as described in the relevant section of the Participant Information Sheet about future unspecified research. This research may include investigation of other inflammatory mediators.

☐ Yes, I agree to allow blood and urine to be stored and used for future unspecified research, as described above.

☐ No, I do not agree to allow blood and urine to be stored and used for future unspecified research, as described above.

Name of Participant (please print)	Signature of Participant	Date

Declaration by Senior Researcher†

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

Name of Senior Researcher (please print)	Signature	Date

† A senior member of the study team must provide the explanation of, and information concerning, the study.

Witness to consent (If applicable)

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. If an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.*

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Withdrawal of Treatment or Participation Form

Completion of this form is OPTIONAL. By completing this form, you will help the study team to document your decision to withdraw from the study. You may withdraw verbally if you prefer.

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Site:	Hunter Medical Research Institute (HMRI), The University of Newcastle

Declaration by Participant

With regards to my participation in this study, I hereby wish to (**select one option only**):

Study Data

☐	Withdraw from study treatment but I will allow access to my medical records for continued collection of my health information **OR**
☐	Withdraw from study treatment AND I withdraw my consent for the collection of any future information from my medical records

I understand that such withdrawal will not jeopardise my future health care.

I understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with HMRI or The University of Newcastle.

Name of Participant (please print)	Signature of Participant	Date

Declaration by Senior Researcher†

I declare that the above information is true and correct. I have not sought to influence the participant's decision in completing the withdrawal of consent form. I understand that providing a false declaration is a serious offence.

I have given a verbal explanation of the implications of withdrawal from the research study and I believe that the participant has understood that explanation.

Name of Senior Researcher (please print)	Signature	Date

† A senior member of the study team must provide the explanation of and information concerning withdrawal from the research study.