Participant Information Sheet and Consent Form

Short Name of Study	**The DEFEND Study**
Full Name of Study	**Dietary fibre supplements, inflammation, and immune function in Chronic Obstructive Pulmonary Disease (COPD).** ***An additional study to the ANTIC STUDY: A Nutrition Trial In COPD***
Principal Investigator	Professor Lisa Wood
Study Sponsor	The University of Newcastle
Site Name	Hunter Medical Research Institute

1. What am I being invited to do?

We, researchers at the University of Newcastle, invite you to take part in this research study called the DEFEND Study. This is because you have Chronic Obstructive Pulmonary Disease (COPD), and you are taking part in another study called the ANTIC Study (A Nutrition Trial in COPD).

This study is an extra study to the ANTIC Study. Taking part in our study will not change how you take part in the ANTIC Study. You will come to the Hunter Medical Research Institute (HMRI) for study visits. When you come to the HMRI for ANTIC study visits, we will ask you to do extra tests for this study.

This document tells you about the study and describes what will happen if you take part. Knowing what is involved will help you decide if you want to take part in the research.

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 about it with a relative, friend or local doctor.

If you decide to take part in the study, we will ask you to sign the consent form (the last page of this document). You will be given a copy to keep.

2. What is the purpose of this study?

This is a medical research study for adults who have COPD. It is an extra study for people who are taking part in the ANTIC study (A Nutrition Trial in COPD), which is testing dietary fibre supplements.

We are looking at how the dietary fibre supplements work in your body. We want to find out how fibre affects your lungs and your body's natural defence against illness.

Dietary fibre comes from plant-based foods (oats, beans, fruits, vegetables, grains). When fibre reaches the bowel, the microbes that live there break it down into small compounds. These compounds and the microbes in your gut, link your gut to your lungs. And they can improve the body's natural defence against illness.

This means that dietary fibre supplements might improve lung health and reduce COPD flare-ups (exacerbations).

Around 40 people with COPD will take part in this study. They will be from Newcastle, the Hunter, and Lake Macquarie.

3. What do I have to do if I take part?

If you agree to take part, we will first check in more detail whether the study is suitable for you.

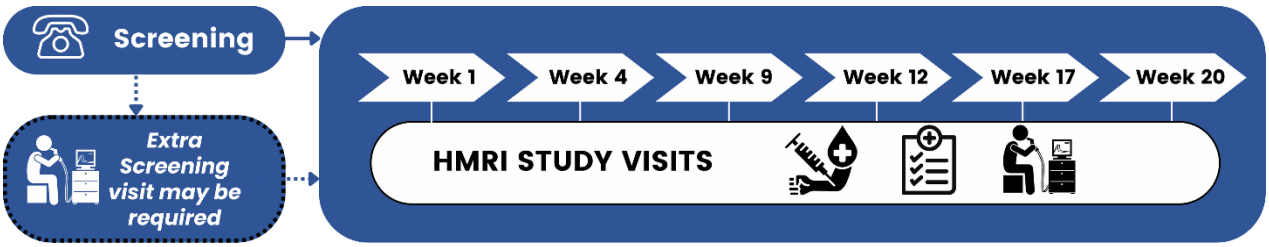
If the study is suitable for you and you agree to take part, you will be asked to sign the Participant Consent Form before you do any study-related tests.

We may tell your local doctor if you take part in this study. Please tell us if you do not want us to do this.

If you take part, you will be in the study for 20-weeks (5 months) in total. **See the picture below for the visit timeline.**

You will attend study visits six (6) times, every 4-weeks, in the Clinical Research Facility at HMRI, New Lambton Heights. These study visits will be on the same day and at the same time as your ANTIC study visits. The tests in this study will add an extra 30 minutes to ANTIC study visits, which may take 2-3 hours.

In addition to the ANTIC study tests, we will ask you to do breathing tests. We will also collect an extra blood sample and a sputum (phlegm) sample from you at each study visit.



Study Visit Timeline

Expenses and reimbursement

If you take part in this study, it will not cost you anything. Parking will not cost you anything at HMRI. A parking space will be reserved for you at each study visit.

We will reimburse you for some of your out-of-pocket expenses during the study. We will reimburse you with a $20 gift voucher at each visit to cover travel costs. This reimbursement is separate to, and not affected by any reimbursements that you may receive from taking part in the ANTIC study. We will email you an electronic gift voucher for each study visit.

The table below outlines what you need to do in this study. For more information about each test, please see the next section 'What do the study tests involve?' below, or please ask a member of the study team.

What part of the study?	What do I have to do?
Before you start the study	We will need to check that the study is suitable for you. We will call you and ask questions over the telephone about the medicines you take and your medical history. If this study is right for you, and you would like to take part, we will ask you to sign the Consent Form.
When you start the study	We may ask you to come in for an extra study visit if we need to check your COPD diagnosis. If you come in for a screening visit, we will: • Check your body weight and height • Measure your lung function (around 1 hour)
During the study	At each study visit we will: • Ask you to fast for 12 hours before you come in • Collect a blood sample from you • Measure your lung function • Collect a sputum sample from you during a breathing test • Check your body weight (around 1.5 hours)
At the end of the study	We can send your results, including breathing tests, to your doctor at the end of the study, if you wish.
After the study finishes	We will send you a plain language summary of the results of the study, if you agree.

4. What do the study tests involve?

Blood test

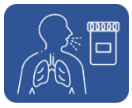
We will collect a blood sample (about 1.5 tablespoons or 27mL). Before you come in, please do not eat or drink anything other than water for 12 hours. We will collect the blood sample from a vein in your arm.

You will be offered a snack after we collect your blood.

Lung function test (Spirometry)

We will ask you to blow into a machine to measure your lung function. This machine measures the amount of air you can breathe out of your lungs. You will blow into the machine until your lungs are completely empty (about 6 seconds).

This is a safe and routine breathing test. You may feel short of breath and/or dizzy, but this usually only lasts for a few seconds.



Sputum test

In this breathing test we will ask you to breathe in a small amount of powdered sugar, called Mannitol. You will breathe in the powder through a dispenser like an inhaler, then we will measure your lung function. You will repeat the test up to a maximum of 9 times, with larger doses of powder each time. During the test, we will ask you to cough up sputum (phlegm) from your lungs into a jar.

This is a routine test, which allows us to look at what is happening in your lungs. We will stop the test if you want to, or if you have any problems with your breathing.

Before the test, and if you have any problems with your breathing, you will be given a reliever medication (Ventolin). Ventolin is a medication that quickly relieves tightness in your chest. You will inhale the medication through your mouth using a spacer.

We will closely watch your symptoms and breathing throughout the test.

Body weight and height

We will measure your body weight using normal scales. We will measure your height by asking you to stand against a ruler on the wall.

We will ask you to take off your shoes and any heavy jumpers/jackets first.

5. Do I have to take part, and can I change my mind?

Taking part is up to you

You get to decide whether you take part in this study. You can say yes or no. You will receive the best possible care whether or not you take part.

Your decision will not affect your relationship with your doctor or any staff at the HMRI, University of Newcastle or the Hunter New England Local Health District.

You can change your mind at any time

If you do take part, you can stop at any time. If you want to stop, please tell someone in the study team that you want to withdraw from the study.

Once you stop taking part, we will not do any more DEFEND study visits, but you can still stay in the ANTIC Study if you want to. We will keep the information and samples we have already collected from you. This is so we can measure the study results properly. Please only join this study if you are happy with this approach.

The study might stop for other reasons

We may also ask you to stop taking part in the study if it is no longer in your best interests. If this happens, we will talk about this with you.

6. 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 coordinator to discuss your decision. Your study investigator will discuss how to manage any health risks and provide recommendations for your ongoing care.

If you decide to withdraw your consent from the study by declining all study procedures 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 coordinator 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.

7. 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.

8. What are the benefits of taking part?

You will help us understand more about the possible health benefits of dietary fibre supplements for people who have COPD. This may help people with COPD in the future.

You may not directly benefit from taking part in this study. However, your lung function and COPD symptoms will be regularly monitored during the study.

9. What are the risks and discomforts of taking part?

There are potential risks to you from taking part in this study.

Risks of study tests

Blood test: You may get bruising where the needle entered 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.

Lung function test (spirometry): This test may make you feel dizzy, breathless or faint, but this usually only lasts for a few seconds. Please tell the research team if you have ever fainted during breathing tests.

Sputum test: You may feel some discomfort in your chest and cough more often during the test. If your lungs are sensitive, you may feel more wheezy, out of breath or tight chested than when you started the test. These symptoms will go away after we give you a reliever medication like Ventolin, in around 5-10 minutes. Serious complications are rare, and risks will be kept to a minimum.

During the sputum test you breathe in a drug called mannitol. All drugs carry at least a small risk of side effects. For mannitol this includes a headache, chest tightness, sore throat, light-headedness, nausea, runny nose, vomiting, or dizziness. There is also an extremely rare risk of allergic reaction.

If you are pregnant, want to become pregnant or you are breastfeeding, you cannot take part in this study. If you think you may be pregnant during the study, please tell us straight away.

10. How will my information and samples be used for this study?

This section tells you how this study will collect, store, use, and share and dispose of your information and samples. If you do not want us to collect this information, you cannot take part in this study.

Collecting your information and samples

We will collect information for the study directly from you, and from the ANTIC Study.

By signing the Consent Form you agree to the study team, collecting, and using personal and health information about you for the study.

Any information that we collect for this study that can identify you will be confidential. We will only tell other people your information if you agree, except as required by law.

Your blood and sputum samples will be sent to our HMRI laboratory for testing. We will ask you if we can keep these samples, without your name on them, for future research (with ethics approval). It's your choice; you can choose to have the samples destroyed at the end of the study. We will not perform any genetic testing on your samples as part of this study.

11. What happens to the information and samples collected from me?

Sharing your information and samples with others during the study

We may share some of your information with these people:

- **Your doctor**: If we find out information relevant for your ongoing care, we will share this information with your doctor or specialist so you can receive the care you need.
- **Other researchers:** If you are enrolled in another study within the HMRI Immune Health Research Program and both studies need the same information from you, you can give us permission to share the data collected during our study with these other researchers to reduce the need for you to have further testing.

Results of blood and sputum tests

These laboratory research tests are experimental, and the results will not be suitable for guiding decisions about your treatment. Because of this, we do not plan to make your individual results from these tests available to you or your doctor.

Keeping your information and samples safe

Personal information (including your name, date of birth and address) will be removed and replaced with a unique study code. Only the minimum, necessary data will be shared with study researchers. This maintains your privacy, while allowing our study team to link any research findings back to you if necessary.

This will be important if there are findings that impact your future health care, so that we can contact you to return these results.

To keep your information and samples safe, we will:

- follow all relevant privacy requirements
- store coded information securely at HMRI and on a secure electronic study database.
- store samples securely in a restricted-access laboratory at HMRI
- take steps to prevent anyone from accessing information or samples that identifies you, unless they are authorised to do so.

You can ask us to tell you what information we have collected about you as part of this study. You can also ask us to change any information that is incorrect. Please contact the study team member named at the end of this form if you would like to access your information.

If you give us your permission, we will keep your information and unused samples for at least 15 years. After this, we will permanently remove any information that directly identifies you but keep your de-identified information and samples.

You have the right to have your samples destroyed at any time by contacting the 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 Newcastle is responsible for destroying the samples at your request.

Publishing study results

We will share certain information from this study so that others can use it and understand the study findings. This information will not identify you individually. We will make this study information available through journal articles and presentations. **By being in this study, you agree to us sharing study information for these purposes**.

12. How will my information and samples be used for future research?

Future Unspecified Research– Optional:

Sharing your study results may help improve new research studies in the future.

The researchers doing this study are interested in doing more research in the future to better understand the nature of COPD. Your study results, and/or the blood and sputum samples collected from you may be used in this research.

We will ask you to consider sharing your study results, including your blood and sputum samples for 'future unspecified research'. This research may not benefit you but may help people in the future who have COPD.

This is optional. If you agree, your samples will be stored for future use for research that is very similar to this study or research that is very different. Any future use would be approved by Professor Lisa Wood 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 HMRI.

The future research would not involve genetic testing and will only occur in Australia.

If your study results, blood, and sputum samples are used in future research, we will take steps to make it difficult for anyone to link this data back to you. This includes removing information that could easily identify you, like your name or contact information.

13. Who is running and paying for this study?

This study is being run by researchers at the Hunter Medical Research Institute (HMRI).

This study is being organised by the Principal Investigator Professor Lisa Wood, and Dr Bronwyn Berthon from the University of Newcastle. This study is an investigator-initiated clinical research project. This means that it is led by researchers, not a commercial company.

The researchers are receiving research funding from an NHMRC synergy grant to help run 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).

14. What happens if something goes wrong?

In an emergency, you should call 000 or go to the emergency department at your nearest hospital. If 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 in arranging appropriate medical treatment.

In the event of loss or injury, the parties involved in this research project have agreed that you may be entitled to seek compensation for any injuries or complications resulting from the study if your injury or complication is sufficiently serious and is caused by the negligence of one of the parties involved in the study (for example, the researcher). You may wish to seek legal advice to explore your options. You do not give up any legal rights to compensation by participating in this study.

If you receive compensation that includes an amount for medical expenses, you will be required to pay for any medical treatment required for your injury or complication from those compensation monies. If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can seek medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital. If you are not eligible for Medicare, you may be able to claim compensation back via your private health insurance.

15. Who has reviewed and approved this study?

This study 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 St Vincents Hospital Sydney Human Research Ethics Committee has approved this study (2024/ETH02517). This is an independent committee that makes sure that this study meets Australian ethical standards for research that involves people.

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.

Comments or complaints about how this study is being run

If you have any concerns or complaints about the way this study is being run, then you may contact:

St Vincent's Hospital Sydney HREC Executive Officer

02 8382 4960

SVHS.Research@svha.org.au

and quote the reference number: 2024/ETH02517.

16. Where can I find more information, and who should I contact?

Thank you for taking the time to read this information about our study. If you would like to know more, please get in touch with the Study Coordinator below. We will talk about the study with you and answer any questions.

Dr Bronwyn Berthon
Study Coordinator
02 4042 0116
Bronwyn.Berthon@Newcastle.edu.au
Immune Health Research Program
Level 2, HMRI Building, Lot 1 Kookaburra Circuit,
New Lambton Heights NSW 2305.

Dr Kurtis Budden
Study Researcher
02 4042 0818
Kurtis.Budden@Newcastle.edu.au
Immune Health Research Program
Level 2, HMRI Building, Lot 1 Kookaburra Circuit,
New Lambton Heights NSW 2305.

Prof Lisa Wood
Chief Investigator
02 4921 7485
Lisa Wood@Newcastle.edu.au
Room 606, Medical Sciences Building
University of Newcastle,
Callaghan NSW 2308

You can find out more information about the ANTIC Study by visiting the Newcastle Site website https://hmri.org.au/antic-study **or scanning the QR code.**

SCAN ME!

17. Can I give my consent electronically or online?

If you wish to take part in the study and would like to give your consent electronically or online using your computer or mobile phone, please use this link: https://redcap.link/defendstudypicf or scan the QR code. You can download or save a copy of your completed consent form when you submit it electronically. Giving your consent electronically is the same as when you sign a traditional paper consent form.

SCAN ME!

Thank you for taking the time to consider this study.

This information sheet is for you to keep.

Consent Form (Our copy)

Short Name of Study	**The DEFEND Study**
Full Name of Study	**Dietary fibre supplements, inflammation and immune function in Chronic Obstructive Pulmonary Disease (COPD)**
	An additional study to the ANTIC STUDY: A Nutrition Trial In COPD
Principal Investigator	Professor Lisa Wood
Study Sponsor	The University of Newcastle
Site Name	Hunter Medical Research Institute

Consent to take part in this study: This means you can say NO

By signing this consent form, I acknowledge that:

- ☐ I freely agree to take part in this study.
- ☐ I understand that I can stop taking part in the study at any time.
- ☐ I have read, or have had read to me, the information provided about this study and understand what is involved, including the use of my personal information.
- ☐ I have had the opportunity to consider the information, ask questions and am satisfied with the answers I received.
- ☐ I consent to my blood and sputum samples taken from me during the study to be used and stored for this study, as described in the relevant section of the Participant Information Sheet.
- ☐ I understand that I will be given a signed copy of this document to keep.

Consent to future use of information and samples (Optional)	**Yes**	**No**
I agree to my study data, blood, and sputum samples being stored, used and shared for future unspecified research, as described in the Participant Information Sheet.	☐	☐
Consent to sharing data with other HMRI studies (Optional)	**Yes**	**No**
I agree to allow other studies that I am enrolled in within HMRI to access data that is the same as the data collected in this study.	☐	☐
I would like a copy of the study results emailed to me (Optional)	**Yes**	**No**
Email address:	☐	☐

Person taking part in the study

Signature: _____ **Date:** _____

Name: _____

Person leading the informed consent discussion

I have explained the research study, its tests and risks to the potential participant and I believe they have understood that explanation.

_____

Researcher Name Signature Date

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Consent Form (Your copy)

Short Name of Study	**The DEFEND Study**
Full Name of Study	**Dietary fibre supplements, inflammation and immune function in Chronic Obstructive Pulmonary Disease (COPD)**
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Principal Investigator	Professor Lisa Wood
Study Sponsor	The University of Newcastle
Site Name	Hunter Medical Research Institute

Consent to take part in this study: This means you can say NO

By signing this consent form, I acknowledge that:

- ☐ I freely agree to take part in this study.
- ☐ I understand that I can stop taking part in the study at any time.
- ☐ I have read, or have had read to me, the information provided about this study and understand what is involved, including the use of my personal information.
- ☐ I have had the opportunity to consider the information, ask questions and am satisfied with the answers I received.
- ☐ I consent to my blood and sputum samples taken from me during the study to be used and stored for this study, as described in the Participant Information Sheet.
- ☐ I understand that I will be given a signed copy of this document to keep.

Consent to future use of information and samples (Optional)	**Yes**	**No**
I agree to my study data, blood, and sputum samples being stored, used and shared for future unspecified research, as described in the Participant Information Sheet.	☐	☐
Consent to sharing data with other HMRI studies (Optional)	**Yes**	**No**
I agree to allow other studies that I am enrolled in within HMRI to access data that is the same as the data collected in this study.	☐	☐
I would like a copy of the study results emailed to me (Optional)	**Yes**	**No**
Email address:		

Person taking part in the study

Signature: _____ **Date:** _____

Name: _____

Person leading the informed consent discussion

I have explained the research study, its tests and risks to the potential participant and I believe they have understood that explanation.

_____

Researcher Name Signature Date

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Withdrawal of Participation Form

Short Name of Study	**The DEFEND Study**
Full Name of Study	**Dietary fibre supplements, inflammation and immune function in Chronic Obstructive Pulmonary Disease (COPD)** ***An additional study to the ANTIC STUDY: A Nutrition Trial In COPD***
Principal Investigator	**Professor Lisa Wood**
Study Sponsor	**The University of Newcastle**
Site Name	**Hunter Medical Research Institute**

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.

You have indicated that you would like to stop taking part in this study and have told this to a member of the research team. You have the right to withdraw from this study at any time. Withdrawing will not prejudice your future medical care. Please discuss your options and intentions with your doctor, study team and relatives before withdrawing.

Declaration by Participant

I wish to withdraw from participating (stop taking part) in this research study.

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

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher will provide a description of the circumstances below:

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	Signature	Date

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