Participant Information Sheet/Consent Form

[Insert site name]

Title	Treatable Traits in Interstitial Lung Disease-Part 2 comparing management of Treatable Traits versus standard clinical care.
Short Title	TTRILD Part 2
Project Sponsor	Medical Research Future Fund
Coordinating Principal Investigator/ Principal Investigator	Professor Yuben Moodley
Location *(where CPI/PI will recruit)*	*[Location]*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project because you have a lung disease that is classed as an interstitial lung disease.
This study is comparing standard practice versus a specially designed Treatable Traits in Interstitial Lung Disease TTRILD program.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments 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 or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you do not have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.

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

2 What is the purpose of this research?

Interstitial lung disease is not one single condition, but a group of different diseases affecting the lungs.

This project will investigate an innovative treatable-trait-based precision medicine approach (TRRILD) to improve the management of Interstitial Lung Disease (ILD).
It directly addresses consumer priorities,[17] as expressed in their most frequently asked questions: ***'What can make me feel better?'*** and ***'How can I live longer?***

The first part of this study looked at the prevalence and management of treatable traits across Australia.

Treatable Traits (TT) are problems that you may experience with your lung disease. Some may be directly related while others are present alongside your ILD. The specific issues that we can identify, and treat are called treatable traits. In this study we will look at a specific group of traits These traits are as follows:

- Cough
- Hypoxaemia – reduced oxygen in your blood.
- Obstructive Sleep Apnoea
- Sarcopenia- loss of muscle mass and function
- Breathlessness
- Osteoporosis
- Anxiety
- Depression
- Fatigue
- Loss of appetite

The study aims to understand which TT are important and to assess whether targeted management of these specific traits versus standard treatment will improve patient outcomes.

This part of the study is to compare the effectiveness of a specially design Treatable Traits in Interstitial Lung Disease TTRILD program versus standard clinical care. The information that is gathered during the research project will be used to improve care for people with ILD.

TT are well described in airway disease (e.g. asthma), they have never previously been defined for ILD.

The TTRILD program we have designed is a world first and will assist in improved management and care for people with ILD.

In summary, this project will generate new knowledge of international significance for personalising the management of ILD and establish the evidence required to begin implementing this new approach in Australia.

The trial protocol has been developed and endorsed by the CRE-PF and the Pulmonary Fibrosis Australasian Clinical Trials network.
This research has been funded by Medical Research Future Fund (MRFF).

3 What does participation in this research involve?

To be eligible for this trial you will need to meet the inclusion criteria. Screening inclusion criteria will require a health history and several questions.

You will be asked to sign the consent for this study before any assessments or blood samples are taken.

You will be participating in a randomised controlled research project. The results are compared to see if one is better.

Your participation in the study will be 6 months after which time you will continue your regular ILD care.

The study will be conducted over a 1–2-year time frame. This is to cover any delays that may occur due to recruitment and scheduling.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid.

You will be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

4 What do I have to do?

All participants will be required to attend 3 clinic appointments at 0, 3 and 6 months

Each participant will complete an assessment at enrolment which will include:

- Demographics (personal details)
- Medical History
- Medications
- Physical assessment
- Previous Investigations

Investigations

- Blood tests including auto-immune screen
- Sputum sample analysis
- Lung function tests: Tests to measure how your lungs work. You will be asked to breathe in and out through a mouthpiece, sometimes after using an inhaler. The tests are safe and usually take 30–45 minutes.
- DEXA scan: A DEXA scan measures bone strength. You will lie on a padded table while a scanning arm passes over your body. It is painless and takes about 10–15 minutes.
- HRCT: A high-resolution CT scan of the chest takes detailed images of your lungs. You will lie flat on a table that moves slowly through the scanner. The scan is painless and usually takes about 10 minutes.

. **Questionnaires to be completed at enrolment**

- KB-ILD, - QOL
- Leister Cough questionnaire - cough
- Stop bang questionnaire - OSA
- Dyspnoea-12 -breathlessness
- Fatigue (FSS) – Fatigue Severity Scale
- Patient-Generated Subjective Global Assessment Short Form – nutritional status
- Anorexia Cachexia Scale
- Perceived Stress Scale (PSS)
- International Physical Activity Questionnaire
- EQ-5D-5L
- HADS Hospital Anxiety Depression Scale
- SARC-F Sarcopenia questionnaire.

You will ask to complete a cost diary for the duration of the study. This will be used to economically evaluate patient costs and health system costs for the TTRILD program versus standard care.

You will be allocated to either.

- Standard clinical care for ILD vs

- The TTRILD program

To try to make sure the groups are the same, each participant is put into a group by chance (random). The decision as to which group you will be allocated to will be done randomly by a computer.

Standard clinical care - the usual care that patients with ILD receive at hospital outpatients' clinics

TTRILD program - At each clinic appointment, you will be assessed by a nurse, physiotherapist, and physician. At the first clinic, you will also be assessed by a psychologist. At the end of the clinic the team will meet to discuss each patient and devise a plan to optimise the management of TTs for that individual. We will determine if expanding the multidimensional assessment of a patient will improve outcomes. This program will require a time commitment to attend sessions for physiotherapy, dietician, and psychology.

Patients seen in TTRILD program will have their clinic appointments at Harry Perkins South (adjacent to Fiona Stanley) during the trial. Because this is not within the Fiona Stanley site if a medical emergency is to occur, an ambulance is required to be called. Any costs associated with this will be incurred by the trial.

In the TTRILD Program participants will have a personalised care plan.

Physiotherapy programs will be tailored to the individual. This will require a time commitment to take part in the program some of which will be done in a physiotherapy gym and some home-based exercises.

Dietician will consist of 3 appointments in the clinic and 2 phone calls at 2 and 4 weeks.

If further psychology support may be beneficial, we will provide you with a recommendation for a free online stress management course, or individual therapy/psychiatry.

If you are allocated to the Standard Clinical care, you will still have access to the allied health consults and programs. Referrals will be done through the usual standard care health referral system.

5 Other relevant information about the research project

The TTRILD program vs standard clinical care study will be conducted at Fiona Stanley Hospital in WA with recruitment also from Sir Charles Gairdner Hospital (SCGH). Patients from SCGH who are recruited to TTRILD program will receive TTRILD care for 6 months at Fiona Stanley and those in standard of care will remain at SCGH.

The trial aims to recruit 110 participants: 55 for the TTRILD Program and 55 for the standard clinical care program.

This part of the study is following on from part 1 which was to evaluate the prevalence and management of treatable traits across Australia. This was a series of questionnaires completed at 4 sites across Australia.

Dr Megan Harrison, respiratory physician will be collaborating on the study as a student, to complete a Doctor of Philosophy through the University of Sydney. Professor Tamera Corte is the student supervisor.
Research data analysis completed by Dr Harrison for her PhD will be stored deidentified securely at the University of Sydney. When data analysis is complete, data will be returned and stored deidentified on the UWA REDCap data base.

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 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 *[Institution]*.

7 What are the possible benefits of taking part?

By taking part in this research, you have a 50% chance of being in the TTRILD program which will give you a multidisciplinary team-based care program personalised to your needs. This program will be innovative and aimed at improving health outcomes for people with ILD.

If you are selected for the Standard Clinical Care group, you will not be disadvantaged.
You will still receive the standard care you would get in attending Fiona Stanley Hospital or Sir Charles Gairdner Hospital outpatient clinic.

Although you may not benefit directly from taking part in this study the information collected will help contribute to future improved care and health outcomes for people with ILD.

8 What are the possible risks and disadvantages of taking part?

Having a blood sample taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated. The blood sample taken is 30ml, which is approximately two tablespoons.

This research project involves exposure to a very small amount of radiation. This is due to the undertaking of a DEXA scan as part of the research. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this research project is about 0.02 mSv. The dose from this research project is comparable to that received from many diagnostic medical x-ray and nuclear medicine procedures. At this dose level, no harmful effects of radiation have been demonstrated, as any effect is too small to measure. This risk is believed to be low and, theoretically, is approximately equivalent to a simple Xray

The research will include studies of inherited (genetic) factors. This is a blood sample that will be used to test DNA. There are important considerations for genetic testing that are listed below

- You will be informed of the results by the investigating doctor. You can decide not to be informed if you wish.
- This is not general health test.
- The results are based on current knowledge that may change in the future.
- This test will not predict all future health problems.
- You can change your mind about receiving the genetic test results at any time by contacting the investigating doctor.
- There are a number of different results from testing, and these can have implications for you and your family. If a genetic condition is found that may impact yourself and/ or your family members you will be referred on to the genetics clinic at King Edwards memorial Hospital (KEMH). This is a targeted genetic clinic that is run as part of the public hospital system and will not be of cost to you. As KEMH is the only public genetic counselling service, the wait list can be lengthy. You may instead choose to access a private genetic clinic, though this may incur a cost."A positive result may result in your family members being referred for additional assessment or review in a respiratory clinic.
- The results may be of “unknown or uncertain significance” which means they cannot be understood based on current knowledge. These results are not passed on to yourself or your medical team.
- There is a chance that some genetic tests could identify other medical conditions (or susceptibility to other medical conditions) as an incidental finding.
- The genetic tests may identify unexpected family relationships.
- The genetic tests may affect your ability to obtain some types of insurance (for example, life insurance).
- Further testing may be needed to finalise the result.
- The reason for testing and the potential benefits and limitations involved in the testing have been explained to you in a way you can understand.
- You have an opportunity to discuss the information, ask questions and have any concerns addressed and you are satisfied with the explanations and answers to your questions.
- Your results are confidential and will only be released with your consent or as required or permitted by law. Information you share with a psychologist during this study will be kept confidential, unless we are concerned you may be an immediate danger to yourself or others, or are otherwise legally required to break confidentiality.

9 What will happen to my test samples?

Blood and sputum samples taken from you will be used for this research project and with your consent used for future research into ILD. The purpose of the laboratory research is to understand more about TT in ILD.

Samples of your blood and sputum obtained for the purpose of this research project will be transferred to Institute Respiratory Health Biobank at Harry Perkins North QEII Medical Centre Verdun Street Nedlands WA. Your blood will not be sold by IRH Biobank however IRH Biobank may charge study doctors a fee to recover some of the costs of storing and administering the samples.

The research will use the latest laboratory tests to identify markers in the blood that will enable a scientifically based approach to predicting progression of ILD before there are changes in the lung function.

The samples for genetic testing will be de-identified prior to transfer to the University of Tasmania They will be stored de-identified and secured confidentially. The samples will be kept for a period of 15 years after which time they will be destroyed.

You will retain the right to have your samples destroyed at any time by contacting your study doctor. 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 central laboratory at Insttitute of Respiratory Health is responsible for the destruction of all of your remaining samples at your request. Otherwise, your samples will be stored for use towards the above purposes.

If you decline consent for future research, your blood and genetic samples will be stored

10 Can I have other treatments during this research project?

Taking part in this study does not require any changes to your normal care and medications.

11 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw.

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

12 What happens when the research project ends?

At the end of the study your standard clinical care will continue at FSH.

A description of the study will be available at http://www.clinicaltrials.gov. This website will not include any information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

At the end of the study you may receive the study results including any publication(s) requested from the research team.

Part 2 How is the research project being conducted?

13 What will happen to information about me?

By signing the Consent Form, you consent to your study doctor and relevant research staff collecting and using personal information about you for the study. Any information obtained in connection with this study that can identify you will remain confidential. The information collected in this study will be identified by a code number. Only your study doctor and the study team will be able to link the code number to you personally. Your information will be included in the study database for analysis. Your information will only be used for the purpose of this study and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form, you agree to the research team accessing health records if they are relevant to your participation in this research project.
Your personal details and all study data will be held by the research organisation. All data collected will be held securely. All study-related documentation at the study sites will be maintained for 15 years following completion of the study. The documents will be archived securely as per (*insert site name*) data management policy. Only research staff associated with the study will have access to this material.

Electronic data will be stored in a password protected database on a secure password protected computer. This data will be kept deidentified on the UWA REDCap server. Only research staff associated with the study will have access to the database.

Electronic data will be stored securely on the UWA server.

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. This review may be done by the relevant authorities, the institution relevant to this Participant Information Sheet, *[Name of institution]*, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant research 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,

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or state privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research 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 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.

14 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.

15 Who is organising and funding the research?

This research project has been funded by the Medical Research Future Fund.
No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

16 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 of South Metropolitan Health Service.

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

The trial protocol has been developed and endorsed by the CRE-PF and the Pulmonary Fibrosis Australasian Clinical Trials network. It will be registered at clinicaltrials.gov before commencing.

17 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 on *[phone number]* or any of the following people:

Clinical contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

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]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

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	South Metropolitan Health Service
HREC Executive Officer	Ethics Coordinator
Telephone	(08) 61522064
Email	SMHS.HREC@health.wa.gov.au.

Hospital Letter Head

Treatable Traits in Interstitial Lung Disease Study TTRILD Consent Form

Title	Treatable Traits in Interstitial Lung Disease- Part 2 comparing management of Treatable Traits versus standard clinical care.
Short Title	TTRILD Part 2
Project Sponsor	Medical Research Future Fund
Coordinating Principal Investigator/ Principal Investigator	*Professor Yuben Moodley Principal Investigator]*
Location *(where PI will recruit)*	*Location*

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 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 project without affecting my future health care.
I understand that I will be given a signed copy of this document to keep.
I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to [Name of Institution] concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher†

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/
Senior Researcher† (please print) _____

Signature _____ Date _____

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

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

Hospital Letter Head

Treatable traits in Interstitial Lung Disease - TTRILD

Consent for the collection of Blood samples

I consent to the storage and use of blood and sputum samples taken from me for use, as described in the relevant section of the Participant Information Sheet, please circle yes or no

- This specific research project. Yes No
- Other research that is closely related to this research project Yes No
- Any future research. Yes No

I agree to the use of my samples for genetic testing, as outlined in the relevant Section of the Participant Information Sheet.

Yes No

I wish to receive the results of genetic testing. Yes No

Name of Participant (please print) _____

Signature _____ Date _____

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning the research project.

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

Hospital Letter Head

Form for Withdrawal of Participation - *Adult providing own consent*

Title	Treatable Traits in Interstitial Lung Disease-Part 2 comparing management of Treatable Traits versus standard clinical care.
Short Title	TTRILD Part 2
Protocol Number	5.020231213
Project Sponsor	Medical Research Future Fund or IRH
Coordinating Principal Investigator/	*[Coordinating Principal Investigator/*
Principal Investigator	*{Principal Investigator}*
Location *(where CPI/PI will recruit)*	*[Location]*

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Institution]*.

In doing so I wish to have all blood samples including genetic samples destroyed ☐ *OR:*

The study group may keep my blood samples and use as described in my original consent form ☐

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

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

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

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

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