Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

[Insert site name]

Title	Creating A RIsk assessment biomarker tool to prevent Seasonal and Thunderstorm Asthma
Short Title	CARISTA Study
Project Number	2024.105.
Project Sponsor	The University of Melbourne
Coordinating Principal Investigator	Prof Jo Douglass
Principal Investigator	{Principal Investigator]
Associate Investigator(s) (if required by institution)	[Associate Investigator(s)]
Location (where CPI/PI will recruit)	[Location]

Part 1 What does my participation involve?

Please read this information carefully. Ask questions about anything that you don't 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 local doctor. If you require this information to be translated into your preferred language, we will arrange for qualified phone interpreters to translate this information and we will respond to your queries. Phone interpreters will be paid for by this study and you will incur no costs.

1 Introduction

You are invited to take part in this research project. This is because you may be allergic to ryegrass pollen and suffer from hay fever and/or allergic asthma during springtime. Our previous study (Thunderstorm Asthma In Seasonal Allergic Rhinitis [TAISAR] study) has shown that people who are strongly allergic to ryegrass pollen are at risk of springtime asthma, but we do not know the level of allergy that can predict allergic asthma or sudden thunderstorm asthma. This project aims to answer that question.

This research project aims to recruit people who are allergic to ryegrass pollen and who suffer from hay fever or allergic asthma or thunderstorm asthma to help us better understand who is most at risk of severe asthma due to springtime pollens or thunderstorms in Victoria.

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

Participation in this research is voluntary. If you don't wish to take part, you don't 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 the tests and research 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?

Thousands of people in Melbourne experience surges in asthma attacks during springtime each year which are thought to be due to allergies to pollens in the air. Melbourne has had some of the most severe springtime asthma epidemics in the world. The worst ever occurred on 21st November 2016 when a springtime asthma epidemic following a thunderstorm overwhelmed ambulance and hospital services and led thousands of people to seek emergency asthma care. Tragically, 9 people died because of asthma on that day. It is inevitable that such severe asthma events will recur, therefore the risks to individuals of springtime and thunderstorm asthma need to be better understood so that protective and preventive treatments can be aimed at those most likely to benefit.

We know that many people with hay fever suffer from springtime asthma yet right now, we do not have a way of knowing who is at most risk for springtime asthma. Knowledge from this research project will provide doctors, people living with asthma, and health experts the evidence to drive preventive strategies that can be used at personal, clinic and public health levels to protect people in the future.

We also know that nearly all people who suffer from springtime and thunderstorm asthma have allergy to ryegrass pollen and also have springtime hay fever. But we do not know exactly how to identify those who are at most risk of springtime and thunderstorm asthma attacks amongst the very many people who have ryegrass pollen allergy and hay fever.

Our previous studies suggest that blood tests for allergic antibodies to ryegrass pollen (IgE) are likely to be a good indicator of asthma risk but we don't know the precise level of these antibodies that determines asthma risk. We also know that breathing tests and some other blood tests may also indicate asthma risk.

So, we are hoping this research project will provide us with information that will enable us to identify people most at risk of springtime or thunderstorm asthma. That is why this study is called "CARISTA", meaning "Creating A RIsk assessment biomarker Tool to prevent Seasonal and Thunderstorm Asthma". This information will enable doctors, nurses and other health professionals to identify and deliver preventive treatment to those at most risk of a severe asthma attack so that they can be kept safe. It will also enable people who discover that they are at high risk of springtime and thunderstorm asthma to keep themselves safe.

This research has been initiated by Professor Jo Douglass and has been funded by the Medical Research Future Fund through The University of Melbourne.

3 What does participation in this research involve?

If you agree to take part in this research project, you will be asked to sign this consent form before any of the following study procedures are performed.

The study procedures are:

- Collection of demographic and medical history information, which includes:
    - general information such as age, gender, where you live, the ethnicity you identify with
    - whether you were born in Australia or elsewhere
    - whether your parents were born in Australia
    - whether you smoke cigarettes or vape
    - what health problems you have or have had previously
    - your current medications

- whether you have asthma or hay fever, and if so, how severe this has been for you, if you have ever gone to hospital because of them, and what treatments you take for these.
- Answer a questionnaire to record your asthma and hay fever symptoms.

- Physical examination will be performed to measure and record your height, weight, blood pressure and heart rate.

- You will be asked to do some breathing tests to check the functioning of your lung. This involves:
  - Blowing into a spirometer (breathing machine) as hard, fast and as long as you can so that we can measure your lung capacity. Usually, we ask people to make 3 to 5 breathing efforts so we can be sure we have the best measurement of how large your lungs are and how much air you can push out in one breath.
  - We then give you some puffs of salbutamol (Ventolin™) asthma reliever medication, usually 4 puffs, and then ask you to do the big forceful breaths again. The difference between amount of air breathed out before and after salbutamol is a feature of asthma.
  - For some people in this study, we will be measuring an additional test for nitric oxide in the breath which is also a feature of asthma. This test involves a single gentle breath for about 8 seconds into a different type of machine. This measures the gases, especially nitric oxide in the exhaled breath.

  If you have done breathing tests at an accredited lung function laboratory in the past three months and provide us with permission to obtain those results for this research project, then we would be able to use these results without repeating this part of the test.

- We will then ask you for 25mls (approximately 1½ tablespoon) of your blood. This will be used in different ways to study the allergic responses in the blood as follows:
  - To study the allergic antibodies (IgE - a type of protein produced by the immune system) in your blood especially to ryegrass pollen.
  - To study allergy to components within ryegrass pollen and understand its link to allergic symptoms
  - To look at the white and red blood cell numbers in a full-blood examination.

  Once we have the results of your blood tests we will know if you are allergic to ryegrass pollen which is the main allergy trigger for seasonal allergic and thunderstorm asthma.

- We will teach you how to use the CARISTA symptom monitoring platform for you to report your asthma and hay fever symptoms and the medications you use for these conditions through an App on either your smartphone, tablet computer or via a website on your computer. This is additional to routine care and is specific to this research project.
  - The CARISTA symptom monitoring platform will be used for you to make a daily diary of your hay fever and asthma symptoms, how severe they are and the medications you use.
  - The CARISTA symptom monitoring platform is not monitored in real-time or after-hours. If you are experiencing severe asthma symptoms, please consult with your/a doctor or seek emergency care if symptoms are very severe, as soon as possible.
  - If you have a smartphone or computer tablet we will ask you install an App on your device. This App is linked to our secure research database held at the University of Melbourne. Data will be downloaded every two hours and data will not be stored on your device.
  - We will ask you to do this every day during the 12 -week period from the beginning of October to the end of December.

- Your report will also tell us if you have hay fever or are suffering from asthma symptoms and how bad they are.
- We will ask you about your approximate location (suburb or postcode or town) at the time you enter your report.
- If you report worsening asthma symptoms during the season, one of the study team will be in contact with you to ask some questions about your asthma and to make sure you are okay. At that time, we may recommend you see your local doctor or seek further treatment.
- The CARISTA symptom monitoring platform will automatically send you a reminder if you have not entered your report by 8.00 pm every evening.
- At the end of the season we will link your symptoms with local information on pollen counts, air quality, temperature and weather changes.

- If you don't have a smart-phone, tablet computer or computer and want to participate in the study, we would ask that you consent to be contacted weekly by phone to answer some questions about your asthma and hay fever symptoms and medication use.
- We will also ask you to participate in logging your symptoms in the CARISTA symptom monitoring platform for a second springtime season (from the beginning of October to end of December) the following year. This is to tell us how long the tests we did at the start of the project are useful for. We will remind you by email and phone from the middle of August of that year about logging your symptoms for the second year. We will inform you of any updates to the CARISTA symptom monitoring platform at that time.

At the end of the first and second springtime recording periods, we will examine the data from everyone in this research project over each springtime season which will allow us to see how hay fever and asthma symptoms were influenced by pollen levels, weather events and air quality. This will help us to better predict those at risk of asthma symptoms in the springtime.

We estimate this research project will entail one visit to the study site clinic where you will be seen by the study doctor and the study nurse. This visit will take about 2 hours. There are no costs associated with participating in this research project, nor will you be paid. You will be reimbursed for any reasonable car parking or public transport expenses associated with the research project visit. This is limited to $55 per participant. For us to do this, you need to keep your parking/transport tickets and give them to the study staff during your visit.

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. For this to happen we will be comparing the information provided to us from study participants who are and are not sensitised to ryegrass pollen.

It is desirable that your local doctor be advised of your decision to participate in this research and of the results of your allergy tests and of your breathing tests. We will provide you with copies of the results of these tests. We will also post separate copies of the results of these tests to your local doctor if you give us permission and provide their name and contact address. Any unexpected abnormal results from these tests will be reported to your study doctor and you will be asked to attend your study site clinic for a follow up to determine the best course of action. This may include a discussion, repeating the lung function and/or blood test/s (at no cost to you), or a referral to a specialist clinic. Your local doctor will also be informed.

4 What do I have to do?

To participate in this research project, you need to be willing to visit the study site clinic for one single visit of approximately 2 hours duration and provide the questionnaire information, breathing tests and blood tests outlined above. We also ask that you record your symptoms for 10 to 12 weeks over springtime (October to December) using the CARISTA symptom monitoring platform every day via the App on your smartphone or tablet computer, or via a

website on your computer. If you cannot access or use a smartphone, computer tablet or computer then we will ask if we can call you once a week to ask your questions about your hay fever and asthma symptoms. You can take all your usual medication, including hay fever medication, and asthma medication after you have enrolled in this research project.

On the day you attend for the testing, we ask that you, if possible, do not take asthma reliever medication for at least 4 hours before the tests. If you have significant asthma symptoms on the day of testing use your asthma reliever and tell the study nurse. Please use your asthma reliever if you are at risk of having severe asthma.

Since this research project is observational and does not change your treatment from that which your usual doctor has prescribed, you can do all the usual things that you would usually do during this study period such as donate blood or exercise. There are no restrictions on your medication use, we just ask you to record your hay fever and asthma symptoms and medications on the CARISTA symptom monitoring platform. If you have any questions, please call the study staff on the phone numbers that will be provided in Section 20 of this form.

5 Other relevant information about the research project

A total of 530 participants will be enrolled in this research project which is being conducted in Melbourne, Victoria. Approximately [insert site target number] participants are expected to take part at [site name]. The research project is a collaboration between investigators at Victorian hospitals (Austin Hospital, Northern Hospital, Western Hospital, Royal Melbourne Hospital, Alfred Hospital, Monash Medical Centre and Eastern Health (Box Hill Hospital), and investigators at the University of Melbourne, Queensland University of Technology (blood allergy tests); and the University of Tasmania and AirHealth (providers of the pollen, air quality and weather information).

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 alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital or clinic. Other options are available; these include not being part of the research project and undertaking your usual hay fever and asthma care as you are advised to do by your doctor and /or pharmacist.

Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

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 having the blood and allergy tests, so you better understand the triggers for hay fever and asthma. Undertaking lung function testing enables a more precise measurement of asthma severity.

If the research project does fulfil its purpose, it will help doctors and public health officers provide information and treatment in the future that may protect those most at risk from springtime and thunderstorm asthma attacks through creating an allergic asthma risk assessment tool.

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

This research does not involve any interventional treatment other than your usual hay fever and/or asthma medications as prescribed by your local doctor or which you purchase from a pharmacy. As you are aware these treatments can be beneficial for hay fever but can also be associated with side effects such as dry mouth or eyes, nose bleeding and oral thrush. You may also suffer from a flare-up of your asthma during the time of this study as it is likely that many of the participants that we have recruited to this research are at risk of springtime allergic and thunderstorm asthma. You will have an asthma plan and treatment to help you manage in such a situation. Should you suffer from severe asthma symptoms that fail to respond to your reliever treatment then you should seek urgent medical help. If you are worried about any side effects or the risk of asthma or hay fever after being enrolled in this research project, talk with your study doctor. Your study doctor will also be looking out for side effects.

Possible risks associated with the study procedures:

Questionnaires and daily completion of a symptom digital platform can be burdensome and for some can provoke unpleasant memories of attacks or severe symptoms. If this happens, speak to your study doctor who can arrange further follow-up with your local doctor.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

You will perform lung function tests. These are generally very safe but they are a test of maximum effort so that some people find them quite tiring to undertake. This usually goes away in a few hours after the visit.

Having a **blood sample** taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated. Some people can feel faint or unwell at the time. If this happens a rest for 30 to 60 minutes is usually required for recovery to occur.

Sometimes some of the tests we undertake, such as the breathing tests or blood tests can uncover something unexpected, such as severe asthma or indicate another disease. If this happens the investigators will talk to you about this. Depending on your response and the seriousness of the condition we would like to then refer you to your local doctor who can arrange further treatment. If the condition appears urgent then we can arrange emergency treatment at the hospital. This treatment would be funded in the usual way by Medicare.

You can participate in this research project even if you are pregnant or breastfeeding.

10 What will happen to my test samples?

Your name and identifying details will be removed from your questionnaire results and blood sample and any paperwork accompanying them and a unique study participant number will be added before they are sent off for testing at the University of Melbourne, the Royal Melbourne Hospital Pathology Laboratory or the Queensland University of Technology. The list connecting your identity and study participant number will only be kept by the study doctor at the site of enrolment and at the study centre at the University of Melbourne (Royal Melbourne Hospital) in a secure research database.

There will be no long-term storage of these blood samples for this study. Samples collected for analysis at the clinical (diagnostic) laboratory will be destroyed as per established institutional guidelines and protocols upon completion of analyses.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information may become available. 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, your study doctor will make arrangements for your regular health care to continue. 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, he/she/they will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you should be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any new medical conditions, treatments or medications you may be taking or which you start during the study, 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.

13 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. 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 up to the time you withdraw will form part of the research project results. If you do not want the investigators 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 if it becomes apparent that a particular treatment is ideal for this condition or the study is no longer needed. This is unlikely to happen.

15 What happens when the research project ends?

After the research project is completed, and all data examined, a summary of the study results will be shared with your study doctor. Your study doctor and/or representatives will share these results with you if you consent to being contacted as outlined in the Consent Form.

A summary of the results may also be published at conferences or in journals. If the results of the study are presented to the public they will be presented as averages over all participants so you will not be named.

Potential future uses of study data: The data that you contribute to this project is highly valued. If required by a journal for publication of the study, the de-identified data file containing analyses and results, may be submitted to the journal publisher. Study data may also be shared in a de-identified form, with an open or mediated access repository, during the publication process. De-identified data may be made available to future research groups who wish to perform secondary analyses (i.e., systematic review/meta-analysis) following completion of the current study. De-identified data may also be used to apply for research grant funds to support ongoing research in this field. De-identified data may also be used by future research projects that are an extension, closely related to, or in the same general area of research as this study. We would like to ask your permission to re-use your research data for future related and unrelated research. Any re-use of the study data, however, will be subject to review and approval by a relevant human research ethics committee.
For some future research, it may not be appropriate or practical to contact you and inform you about the research. For other future research, we may wish to contact you and invite you to participate. You can tell us whether you want us to contact you when you complete the Consent Form for this study.

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 information will only be used for the purpose of this research project 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 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 and authorised representatives of the Royal Melbourne Hospital Human Research Ethics Committee (HREC), the University of Melbourne, 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, except with your permission. Information collected from you will be identified by a special study code. Study identifying codes are kept separate from identifying details in a locked database accessible only to study personnel. This database is kept for 15 years after the study is completed and then securely destroyed. Data collected in the process of this study is analysed only as group data with individual identifying information removed.

Information about your participation in this research project will be recorded in your health records as required by participating hospitals. Your existing medical records will not be used to obtain any information about you for this study. However, if you have done breathing tests at an accredited lung function laboratory in the past three months and provide us with permission to obtain those results for this research project, then we would be able to use these results without repeating this part of the test.

In accordance with relevant Australian and/or Victorian 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 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 has been initiated by Professor Jo Douglass and has been funded by the Medical Research Future Fund through The University of Melbourne.

This research project is being conducted as collaboration between the researchers who will contribute "in kind" their time and expertise. The University of Melbourne will provide funds for work required for the research project, such as processing and sending your sample and regulatory approvals.

[Name of institution] will receive reimbursement for some costs associated with undertaking this study at the study site, such as paying study staff.

Depending on the results that are generated, the research institutions involved in this study may benefit financially from this research project if, for example, it provided doctors and public health experts evidence to support a commercial initiative that could be used at a personal or clinical level to protect people in the future, or as a biomarker for pharmaceutical treatment.

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value.

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 of the Royal Melbourne Hospital.

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.

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 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	Melbourne Health
HREC Executive Officer	Manager HREC
Telephone	(03) 9342 8530
Email	Research@mh.org.au

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

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

Consent Form - *Adult providing own consent*

Title	Creating A RIsk assessment biomarker tool to prevent Seasonal and Thunderstorm Asthma
Short Title	CARISTA Study
Project Number	2024.105
Project Sponsor	The University of Melbourne
Coordinating Principal Investigator/ Principal Investigator	Prof Jo Douglass/ [Principal Investigator]
Associate Investigator(s) (if required by institution)	[Associate Investigator(s)]
Location (where CPI/PI will recruit)	[Location where the research will be conducted]

Consent Agreement

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 [the Name of Institution (Study site)] for the purposes of this project. I understand that such information will remain confidential.

If you have done breathing tests at an accredited lung function laboratory in the past 3 months, do you consent to us obtaining those results if you do not wish to redo your lung function test?

Yes ☐ No ☐ Not applicable☐

I understand the purposes and implications regarding the storage and use of my blood sample for the purpose of this research project.

I consent for my data to be used for future related and/or unrelated research

Yes ☐ No ☐

I consent to be contacted regarding future related and/or unrelated research that seeks to use the research data I provide for this study

Yes ☐ No ☐

Please confirm if you give permission to be contacted regarding participation in future related research projects:

Yes ☐ No ☐

Please confirm if you give permission for us contact you with updates on the study's progress and any research results:

Yes ☐ No ☐

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form

See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9, witness * required

Witness to the informed consent process

Name (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/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.

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

Title	Creating A RIsk assessment biomarker tool to prevent Seasonal and Thunderstorm Asthma
Short Title	CARISTA Study
Project Number	2024.105
Project Sponsor	The University of Melbourne
Coordinating Principal Investigator/ Principal Investigator	Prof Jo Douglass/ [Principal Investigator]
Associate Investigator(s) (if required by institution)	[Associate Investigator(s)]
Location (where CPI/PI will recruit)	[Location where the research will be conducted]

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].

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.