Peter Mac
Peter MacCallum Cancer Centre
Victoria Australia

Place Patient Label Here
(This document must be scanned into the Austin Health SMR once the participant has consented)

PATIENT INFORMATION AND CONSENT FORM

Genetic Study - *Adult providing own consent*

Title	**P**redictors, **I**mmunopathogenesis and **P**rescribing in **A**ntibiotic allergy – A prospective multicentre cohort study
Short Title	PIPA
Protocol Number	
Coordinating Principal Investigator	Dr Jason A Trubiano
Associate Investigator(s)	Prof Lindsay Grayson, Prof Monica Slavin, Prof Karin Thursky, Ms Karen Urbancic, Dr Ar Kar Aung and Prof Elizabeth Phillips
Location(s)	Austin Health, Peter MacCallum Cancer Centre & Alfred Health

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have an antibiotic allergy. You will be asked to donate a sample of blood that will be used for genetic research.

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 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 your local doctor.

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 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 genetic research?

Genes are made of DNA – the chemical structure carrying your genetic information that determines many human characteristics such as the colour of your eyes or hair.
Researchers study genes in order to understand why some people have a certain condition such as antibiotic allergy and why some people do not. Understanding a person's genes also may be able to explain why some people respond to a treatment, while others do not, or why some people experience a side effect and others do not.

3 What is the purpose of this research?

The purpose of the research project is to determine how genetic factors are associated with antibiotic allergies. Genetic factors have been implicated in both allergic disease like eczema, which often runs in families and drug induced allergy, called hypersensitivity or drug hypersensitivity reactions (HSR). Drug HSR may be mild or severe and include symptoms like rash or fever and affect blood cells, the liver and respiratory systems. However, the underlying causes of susceptibility to substances or *allergens* and reactions to them are not well understood. The outcomes of allergy and hypersensitivity have improved as new treatments have been introduced to the health system. However, using genetic tests to determine who is susceptible to allergy may prevent the administration of potentially harmful drugs or the withholding of drugs from those who may benefit, and has the potential to improve clinical outcomes for people who are or could be affected by allergic antibiotic reactions.

The results of this research will be used by the study doctor (Dr Jason Trubiano) to obtain a postgraduate research degree. The study doctor Jason Trubiano has initiated this research program. This research has been funded by a NHMRC postgraduate scholarship grant. This research is being conducted by Austin Health, Peter MacCallum Cancer Centre and Vanderbilt University. There are no pharmaceutical or commercial sponsorships.

4 What does participation in this research involve?

People who have a history of allergy or have experienced an antibiotic reaction are invited to join this research by donating a single blood sample of 100-150ml (maximum volume is approximately 1/3 of a standard blood donation). Some patients may be asked to donate a sample of skin and/or blister fluid. The skin biopsy takes a small piece of skin (less than 2cm) after a small amount of anaesthetic (lidocaine) is injected to numb the area beforehand. The desired skin will be circled and a disposable 3mm punch biopsy will be used to remove a small part of skin. If there are blisters present they will be punctured with a needle and the fluid collected with a syringe. Some patients may be asked to donate a further skin or blood sample at a subsequent clinical visit.

A health professional will also take some of your details. For example, your age, height, weight, ethnic origin, allergy history, past medical history, current medications, alcohol and smoking history. If you have a drug allergy, details will be taken from your case notes regarding the drug/s that caused the reaction, other drugs taken at that time and also the side effects that you suffered. You will be contacted on three occasions following the allergy assessment (1 month, 3 months and 12 months). This phone contact will take 5 minutes to complete and ask about your allergies following assessment. 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. Any medication, tests and medical care required as part of the research project will be provided to you free of charge.

5 What do I have to do?

The only requirement to participate in the study is the blood donation, blister fluid sample and/or skin biopsies as previously described as previously described. No physical restrictions or dietary

restrictions are required. Regular medications should be taken and you can still donate blood (if applicable). There are no restrictions for taking part in this research.

6 Other relevant information about the research project

We estimate that 75 participants will be taking part in this research. There will be participants that have the blood test that do not have a positive allergy test or history of antibiotic allergy (controls). There are three Victorian hospitals involved in this research (Austin Health, Alfred Health and Peter MacCallum Cancer Centre) and researchers from collaborating hospitals at Vanderbilt University (Nashville, USA) will be involved in the testing procedures and interrupting of the results. This is a follow on study from the introduction of antibiotic allergy assessment clinics at Austin Health and Peter MacCallum Cancer Centre. The project involves collaboration between members of Austin Health, Alfred Health, Peter MacCallum Cancer Centre and Vanderbilt University.

7 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 Austin Health, Alfred Health or Peter MacCallum Cancer Centre.

8 What are the possible benefits of taking part?

This research may have benefits to science and humankind. The research may inform and improve the safety of current antibiotic use and future antibiotic development and result in improved safety for people taking medicines for common and uncommon illnesses. We cannot guarantee or promise that you will receive any benefits from this research.

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

The blood test or blister fluid aspiration may be associated with bleeding around the blood draw/aspiration site or collection of blood products under the skin. The skin biopsy may be associated with bleeding or infection around the site of collection. Lidocaine, a numbing drug, may burn or cause a rash, redness or soreness where, you get the shot. The samples can be taken the day of a routine clinic appointment to avoid inconvenience.

Genetic testing involves the study of genetic material (typically DNA) that is shared with your blood relatives. Genetic research is undertaken for many reasons, including discovering more accurate ways of predicting disease within a group of people, or in people where there is strong family history or predisposition of disease. In this case the genetic testing is being performed to look at a select group of genes that are associated with our immune response to proteins of our self or environment. The genetic material and data may have uses unrelated to research. Your genetic material can be removed from the study at your request at any stage.

Genetic testing may raise important issues. Although few may be expected to arise, your awareness of this is important for you to think about and carefully consider before participating.

10 What will happen to my test samples?

We would like to store your samples for future use in research projects that are an extension of this research project. Alternatively we may use your sample for future research that is closely related to the original research project or as a control blood sample. These samples will be stored indefinitely in a locked laboratory at Austin Health. Only the study doctors will have access to

these samples, and they will only be used for research into antibiotic allergy. Further information can be found in this document's section on banking.

11 What is the potential impact on my family if I take part?

You may be asked to give us health information about your relatives. Any information you give us will be kept confidential. We will not contact your relatives without permission. We many discuss with you the possibility of including your relatives in the research project in the future. If the research discloses that one of your family members may be at risk of a life-threatening or serious illness for which treatment is available or pending, this information may, with the prior approval of a Human Research Ethics Committee, be offered by the study doctor to the family member, even if you as the participant do not consent to this.

12 Will I be given the results of the research project?

You will not be given your genetic test results because the research is still in an early phase and the reliability of the results is unknown. If the results were to be validated by future research and a clinical role was established these results will be provided to you, if you are agreeable at that point in time.

13 Will drug or biotechnology companies be able to use my sample for profit in the future?

No.

14 Banking (Long term storage of samples)

"Banking" is storing health information and/or blood or tissue for future research studies. A "bank" is the place where the health information and/or blood or tissue is stored. Your blood and/or tissue will be stored in coded form. The study doctor seeks your permission to store your blood sample for future research. The study doctor would like you to consider taking part in this bank because you have an antibiotic allergy. In the future the nominated study doctors and hospitals (Austin Health, Alfred Health, Peter MacCallum Cancer Centre and Vanderbilt University) may use your blood or tissue samples to learn more about immune responses in antibiotic allergy. Their goal is to improve health outcomes and develop new treatments. The research performed could include further testing of your immune response to antibiotics and genes that encode immune proteins. The study doctor will store your blood, skin and/or blister fluid samples following collection. Your samples will be stored along with samples of many other people. The long term storage of samples will only occur at Australian sites, Austin Health or Peter MacCallum Cancer Centre. The purpose of storing your samples in a bank is to answer questions in the future, so we expect to keep your samples for a long time.

Your blood sample will be stored at Austin Health or Peter MacCallum Cancer Centre. Your sample will be stored in coded form. You can have it removed, destroyed or returned to you by contacting the study doctor, Dr Jason Trubiano, in writing at Austin Health, 145 Studley Road, Heidelberg VIC 3084.

15 What are the possible benefits of banking my blood and/or tissue sample?

There is no direct benefit to you. Other people might benefit if researchers learn more by using your banked blood sample

16 What are the possible risks and disadvantages of banking?

This procedure forms part of the main research project. There is no extra physical risk to you as part of the research.

17 Will I be informed of results of future research using my biospecimen?

If new clinically important information related to studies performed from biobanked specimens become known to study doctors, you will be told about this new information and study investigators will discuss whether this new information affects you.

18 Banking of Health Information

The health information we will collect and store in a bank for this research project is age, sex, country of birth, ethnicity, past medical history, drug history and allergy history. We will not use your personal health information for a different research project without the permission of a Human Research Ethics Committee. Once all personal identification is removed, the information might be used or released for other purposes without asking you. Results of the research project may be presented in public talks or written articles but information will not be presented that identifies the participant.

Part 2 How is the research project being conducted?

19 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 be entered into the database as a study number with no personally identifiable information. Only study investigators will have access to it. 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 your participation in this research project may be recorded in your health records. In the future, your blood sample and genetic material may be used by the study doctors as part of the search for a genetic cause of antibiotic allergy. The samples will be labelled as described in Part 1 of this document. Your sample will have all identifiers (e.g. name and personal details) removed and replaced with a code. It will be possible to re-identify the sample as yours using the code. The study investigators will have this information. Your samples and data will not be released for any use without your prior consent, unless required by law.

Your health records and any information collected and stored by the study doctor during the research project may be reviewed for the purpose of verifying the procedures and the data. This review may be done by the ethics committee, which approved this research project, regulatory authorities, or as required by law. In these circumstances by signing the consent form, you authorise release of, or access to, this confidential information as noted above. In accordance with relevant Australian and Victorian state privacy and other relevant laws, you have the right to request access to your information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

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 express permission.

20 Who is organising and funding the research?

This research project is being conducted by Dr Jason Trubiano of Austin Health, Alfred Health and Peter MacCallum Cancer Centre. 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 to Austin Health, Alfred Health or Peter MacCallum Cancer Centre. In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the study doctors or their institutions, there will be no financial benefit

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

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

23 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 that may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on (03) 94966676 or any of the following people:
Dr Jason Trubiano, Phone: (03) 94966709
Prof Lindsay Grayson, Phone: (03) 94966675
Prof Monica Slavin, Phone: (03) 8559 7995

Clinical contact person

Name	Dr Jason Trubiano
Position	Infectious Diseases Physician
Telephone	(03) 94966676
Email	Jason.trubiano@austin.org.au

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

Complaints contact person

Name	Research Governance Officer
Position	Manager, Office for Research Governance
Telephone	(03) 8559 7540
Email	*ethics@petermac.org*

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	*Austin HREC*
HREC Executive Officer	Dr Sianna Panagiotopoulos
Telephone	(03) 9496 4090
Email	*ethics@austin.org.au*

Consent Form

Title	**P**redictors, **I**mmunopathogensis and **P**rescribing in **A**ntibiotic allergy – A prospective multicentre cohort study
Short Title	PIPA
Coordinating Principal Investigator	Dr Jason A Trubiano
Associate Investigator(s)	Prof Lindsay Grayson, Prof Monica Slavin, Dr Ar Kar Aung and Prof Elizabeth Phillips
Location(s)	Austin Health, Alfred Health & Peter MacCallum Cancer Centre

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 Austin Health concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

In respect to the blood and tissue collection I give permission for:

1. Blood draw Yes ☐ No☐
2. Skin biopsy Yes ☐ No☐
3. Blister fluid aspiration Yes ☐ No☐
4. Follow up blood draw Yes ☐ No☐
5. Follow up skin biopsy Yes ☐ No☐

In respect to receiving information in relation to my genetic materials:
If research with my DNA and/or tissue reveals some other medical condition relating to me or my family for which treatment is available or pending:

a. I wish to be informed Yes ☐ No☐

b. I wish for affected family members to be informed and I give my consent for the researcher to approach my relatives on my behalf Yes ☐ No ☐

In respect to the storage and use of my genetic samples, I give permission for the use of my DNA and/or tissue for the purpose of:

1. this ethically approved research project only Yes ☐ No ☐

2. this ethically approved research project, biobank storage and any closely related future research projects Yes ☐ No ☐

3. this ethically approved research project, biobank storage and future research projects that may or may not be related to this research project Yes ☐ No ☐

I understand that I can withdraw my consent to participate in this research project by completing a "Withdrawal of Consent" form. I can also specify whether I wish to have my blood sample that has already collected and stored, deleted, destroyed or returned to me if it is still identifiable as mine.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

Name of Participant (please

Signature _____ Date _____

Name of Witness* to Participant's Signature (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.

Form for Withdrawal of Participation

Title	**P**redictors, **I**mmunopathogensis and **P**rescribing in **A**ntibiotic allergy – A prospective multicentre
Short Title	PIPA
Protocol Number	
Coordinating Principal Investigator	Dr Jason A Trubiano
Associate Investigator(s)	Prof Lindsay Grayson, Prof Monica Slavin, Dr Ar Kar Aung and Prof Elizabeth Phillips
Location(s)	Austin Health, Alfred Health & Peter MacCallum Cancer Centre

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 my relationship or me with Austin Health. I request that all my blood, skin and/or blister fluid sample collected and banked be deleted, destroyed or returned to me if it is still identifiable.

Name of Participant (please _____

Signature _____ Date _____

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.