Austin Health

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Participant Information Sheet/Consent Form

Non-Interventional Study

Austin Health

FAH018178

Title	Epidemiology of Primary Biliary Cirrhosis in
Short Title	PBC Study
Protocol Number	2013.04857
Project Sponsor	Austin Medical Research Foundation
Coordinating Principal Investigator/ Principal Investigator	Associate Professor Paul Gow/Dr Janine French
Associate Investigator(s)	Professor Peter Angus/Dr Ingrid Van der Mei
Location	Austin Hospital

1. Introduction You are invited to take part in this research project, Epidemiology of primary biliary cirrhosis (PBC). This is because you have primary biliary cirrhosis. The research project is aiming to identify risk factors for Primary Biliary Cirrhosis.

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.

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.

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?

At this stage little is known about the risk factors for Primary Biliary Cirrhosis and we aim to identify them. This will enable us to have a better understanding of the disease and may lead to the development of potential treatments in the future.

3. What does participation in this research involve and what are the risks?

The study involves a visit to the Austin Hospital (145 Studley Rd Heidelberg) or Banyule Community Health (21 Alamein Rd, West Heidelberg 3081) which will take between 1-1/2 hours. If you are unable to travel this distance then the study investigators will be able to come to your local community health centre. The study involves completion of a questionnaire (with assistance from a study investigator) which will take approximately one hour and the investigator will assess weight, height, blood pressure and skin type (on the upper inner arm, and back of the hip using a spectrophotometer.)

The study also involves a small blood sample (35ml) to be taken by a medically qualified person. This is an optional component of the study. Possible adverse effects are discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

The blood sample and will used for vitamin D, viral, antibody and cytokine (substances that indicate immune function) measurements. In addition, DNA testing will be performed to examine genetic factors associated with phenotype (physical characteristics), especially skin type, and causes of immune disorders. This analysis may or may not reveal information of potential importance to your future health in that genetic abnormalities may be detected which may be relevant for you or your offspring. If this is the case this will be communicated to you and explained in further detail by the study investigators. If you provide consent the blood sample will be stored indefinitely and may be used for future related research.

The study also involves having a silicone cast made of the back of your hand, which will be used to determine skin texture. This may cause some discomfort as the back of the hand has a large number of hairs.

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.

4. What do I have to do?

There are no dietary, lifestyle restrictions and you can continue to take all regular medications. You can still donate blood when participating in this study. Whilst participating in this research project you can continue to have all your usual medications and do not need to alert the study investigators if your medications change during this time.

5. Other relevant information about the research project

This study is Australia wide and involves 200 participants (people with Primary Biliary Cirrhosis) and 200 controls (participants without Primary Biliary Cirrhosis.)

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 data will be allocated a code and therefore will be able to be identified by the study investigators.

6. Do I have to take part in this research project?
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 *the Austin Hospital.* You do not have to take part in this research project to receive treatment at this hospital.

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.

7. What are the possible benefits of taking part?
There will be no clear benefit to you from your participation in this research however possible future benefits may include identification of risk factors for primary biliary cirrhosis and potential treatments.

8. What will happen to my information and test samples?
Information obtained from questionnaires will be coded and will be re-identifiable and will be stored in a password protected document only accessible to the study investigators. Serum samples will be coded and will be re-identifiable and will be stored in a locked fridge within the department of gastroenterology.

The blood sample may also be used for future analysis and for future related studies on primary biliary cirrhosis. If consent for future research use is declined the blood samples will be disposed of after twelve months following completion of the research.

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.

9. 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. Withdrawing from the project will involve sending a withdrawal of consent form to the study investigators. 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 investigators 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.

10. Could this project by stopped unexpectedly?
This project could be terminated before completion due to inadequate funding. All participants will be notified if this is the case.

11. What happens when this research project end?
In accordance with relevant Australian 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.

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. If you wish, the researchers will provide you with a published medical journal article of the research findings.

12. What will happen to my information?

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. All information will be stored in a de-identified form. 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.

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.

13. Complaints and compensation

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

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.

14. Who is organising and funding this research?

The results of this research will be used by the study doctor Dr Janine French to obtain a Doctorate of Medical Science. This research has been initiated by the study doctor, Associate Professor Paul Gow. This research has been funded by Orphan Pharmaceuticals. This research is being conducted by the Austin Hospital Gastroenterology and Hepatology Department.

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 Austin Hospital.

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.

15. Further information and who to contact

Clinical contact person

Name	*Janine French*
Position	*Study Investigator*
Telephone	*9496 5353*
Email	*Janine.french@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	*Associate Professor Paul Gow*
Position	*Deputy Director Department of Gastroenterology and Hepatology*
Telephone	*9496 5353*
Email	*Paul.gow@austin.org.au*

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 Health*
HREC Executive Officer	*Lisa Pedro*
Telephone	*9496 4035*
Email	*ethics@austin.org.au*

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

Name	*Sianna Panagiotopoulos*
Position	*Manager of the office for research*
Telephone	*9496 5088*
Email	*ethics@austin.org.au*

Glossary

Spectrophotometer = a device which accurately measures skin colour

Antibody= a large protein produced by the immune system to identify and neutralize foreign objects such as bacteria and viruses.

Cytokine= substances that indicate immune function

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Consent Form - *Adult providing own consent*

Title	Epidemiology of Primary Biliary Cirrhosis
Short Title	PBC Study
Protocol Number	2013.04857
Project Sponsor	Austin Medical Research Foundation
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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 consent to the optional blood test of 35 mls and understand the potential genetic implications

☐ I consent to the future use of this information for related projects at Austin Health

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. 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.

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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.

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

FAH018178

Title	*[Epidemiology of Primary Biliary Cirrhosis in Australia]*
Short Title	*[PBC Study]*
Protocol Number	*[Protocol Number]*
Project Sponsor	*[Orphan]*
Coordinating Principal Investigator/ Principal Investigator	*[Associate Professor Paul Gow/Dr Janine French]*

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 Austin Health.

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.