

Participant Information Sheet/Consent Form: Opt-out For patients receiving treatment at Austin Health

Title	Immune-related adverse events following immune checkpoint inhibitors for cancer: the Australian Registry for Evaluation of Immune-related Severe Adverse events from Monoclonal antibody Immune Checkpoint inhibitors (Aus-REISAMIC)
Short Title	Immune-related adverse events following immune checkpoint inhibitors: the Aus-REISAMIC registry
Protocol Number	1.0
Coordinating Principal Investigator/ Principal Investigator	<i>Russell Buchanan</i>
Associate Investigator(s)	<i>David Liew, Albert Frauman</i>
Location	<i>Austin Health</i>

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have experienced a side effect from the immune checkpoint inhibitor class of medications. The research project is aiming to find out more about what side effects from immune checkpoint inhibitors look like.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the research involved. Knowing what is involved will help you decide if you do not wish 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 do not wish to take part, please mention this to the doctor who supplied this to you, or contact the following person:

Dr David Liew, Associate Investigator, Aus-REISAMIC
(03) 9496 5486
Department of Clinical Pharmacology and Therapeutics
Level 5, Lance Townsend Building
Austin Hospital, 145 Studley Road, PO Box 5555, Heidelberg VIC 3084
david.liew@austin.org.au

2 What is the purpose of this research?

Immune checkpoint inhibitors are a new class of cancer medication. They are in the category of immunotherapy, which means that they activate the immune system (the body's defence system) in order to attack the cancer. In activating the immune system, as a side effect they can also attack unrelated parts of the body, creating inflammatory problems called autoimmune disease. Very little is known about these autoimmune side effects and how they might be best treated.

This research is designed to describe the side effects that patients experience after receiving immune checkpoint inhibitors and to see how they respond to treatment.

3 What does participation in this research involve?

Your treating doctor will pass on information to the study investigators. This information will relate to your general medical history, cancer history, treatment history and any side effects you experienced which may be related to treatment. Your treating doctor may be contacted in future to determine how your cancer treatment and side effects are going.

As part of routine clinical management of side events at Austin Health, your information will be referred to the Adverse Drug Reaction Committee run by the Pharmacy Department. Representatives of this committee may contact you regarding further information. The committee may also report this side effect to the relevant government organisation, the Therapeutic Goods Administration. This report would be deidentified and completely confidential.

This research does not involve any change to your medical care, including your cancer care. Feedback may be given to your treating doctor.

This research does not necessitate any further involvement from you. Through this registry, you may be identified as being suitable for further research projects, and you may be approached directly to see if you are happy to be part of any such research. Involvement in these future research projects is voluntary and you can decide at that time whether you wish to be part of those projects or not.

4 What do I have to do?

If you are happy for your information to be part of the research, you do not have to do anything.

If you wish to opt-out of the research, please contact the investigator listed at the bottom of the first page (Dr David Liew).

5 Other relevant information about the research project

This research is being co-ordinated by the Department of Rheumatology and the Department of Clinical Pharmacology and Therapeutics at Austin Health, Melbourne, in collaboration with the Olivia Newton-John Cancer Wellness and Research Centre and the Pharmacy Department at Austin Health. The results of this research will be used by the study doctor, Dr David Liew, to obtain a Doctor of Philosophy degree.

This research is being performed as part of a collaboration with an existing, similar registry in France called REISAMIC (Registre des effets indésirables sévères des anticorps monoclonaux immunomodulateurs en cancérologie) based at Gustave Roussy Cancer Centre in Paris, France.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you wish to withdraw, please contact the investigator listed at the bottom of the first page (Dr David Liew). If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

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.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include not reporting the adverse event at all, or only reporting the adverse event to the Adverse Drug Reaction committee.

If you wish to opt-out of this study and access these alternatives, please contact the investigator listed at the bottom of the first page (Dr David Liew).

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 a better understanding of your adverse event which may lead to better treatment of these adverse events in the future.

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

While this research does not involve any interventional treatment, you may be receiving medical treatments that cause side effects. If you notice side effects, or are worried about them, talk with your treating doctor. Your treating doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your doctor may need to stop your treatment. Your doctor should discuss the best way of managing any side effects with you.

Viewing your existing clinical information may help to better interpret and clarify the nature of your side effect. If so, we will let your treating doctor know of our interpretation. No new clinical information from you will be obtained during this study.

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.

10 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not 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 treating doctor about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your treating doctor about any changes to these.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

By remaining in the project, 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. This information will be de-identified, and stored securely. 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 remaining in this project, 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, the institutions relevant to this Participant Information Sheet, Austin Health or the University of Melbourne, 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, both on its own and in combination with other registries such as REISAMIC. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Information about your participation in this research project may be recorded in your Austin Health health record.

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.

If any additional use of your information is contemplated in the future, specific consent will be sought for that additional use.

Any information obtained for the purpose of this research project and for any future research stemming from this 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.

12 Complaints

If you have any complaints about your medical care at Austin Health, you should contact the Austin Health consumer liaison officer in the Centre for Patient Experience on (03) 9496 3566, or discuss this with your treating doctor.

If you have any complaints about the way this research project is conducted, you may contact the investigator listed at the bottom of the first page (Dr David Liew).

If you wish to contact someone separate from the team of investigators, you may contact the Austin Health Ethics and Research Governance enquiries office listed on the final page.

13 Who is organising and funding the research?

You will not benefit financially from your involvement in this research project even if, for example, this information does prove to be of commercial value to the University of Melbourne.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the University of Melbourne, 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).

14 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.

15 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, you can contact the principal study doctor:

Clinical contact person

Name	<i>David Liew</i>
Position	<i>Associate Investigator</i>
Telephone	<i>(03) 9496 5486 (03) 9496 5000 (for enquiries outside of office hours)</i>
Email	<i>david.liew@austin.org.au</i>

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	<i>[Name]</i>
Position	<i>[Position]</i>
Telephone	<i>[Phone number]</i>
Email	<i>[Email address]</i>

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	<i>Austin Health HREC</i>
HREC Executive Officer	<i>Chelsea Webster</i>
Telephone	<i>03 9496 4090</i>
Email	<i>ethics@austin.org.au</i>

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Opt-Out Form for Withdrawal of Participation

Title Immune-related adverse events following immune checkpoint inhibitors for cancer: the Australian Registry for Evaluation of Immune-related Severe Adverse events from Monoclonal antibody Immune Checkpoint inhibitors (Aus-REISAMIC)

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Protocol Number 1.0

**Coordinating Principal Investigator/
Principal Investigator** *Russell Buchanan*

Associate Investigator(s) *David Liew, Albert Frauman*

Location *Austin Health*

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.