Participant Information Sheet/Consent Form

Royal Prince Alfred Hospital

Title	Melanoma Institute Australia: Melanoma Research Database
Short Title	Melanoma Research Database
Protocol Number	2.0
Project Sponsor	Melanoma Institute Australia
Coordinating Principal Investigator	Professor Richard Scolyer
Location	*Royal Prince Alfred Hospital*

Part 1 What does my participation involve?

1 Introduction

In the 1960s Melanoma Institute Australia recognised the need to systematically capture information about people diagnosed with melanoma and other related skin tumours. We now have the world's largest single-institute melanoma database which has allowed us to make significant input to melanoma research, helping us to better understand the causes of melanoma and to develop more effective treatments for it.

We invite you to contribute your health information to the Melanoma Research Database (MRD). This is because you are being treated by a clinician affiliated with Melanoma Institute Australia. You may have been diagnosed with melanoma, another skin tumour or you may be considered to be at risk of developing melanoma. The database will help researchers to better understand the causes of melanoma and other skin tumours and to develop more effective treatments for it.

This Participant Information Sheet/Consent Form tells you about the Melanoma Research Database and what will be involved. Knowing this will help you decide if you want to take part.

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 database 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, 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 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?

Your health information will be stored in a database of patients receiving medical treatment by a clinician affiliated with Melanoma Institute Australia (MIA).

MIA is a not-for-profit organisation dedicated to preventing and curing melanoma through innovative, world-class research, treatment and education programs. MIA, based at the Poche Centre in North Sydney, is affiliated with the University of Sydney and Macquarie University.

MIA undertakes research relating to the causes, diagnosis, treatment and outcome of patients with melanoma and other skin tumours. MIA research also focuses on prevention and reducing risk for people with high risk of developing skin tumours and melanoma. MRD has been capturing information about people with melanoma since the 1970s and is considered to be the largest single-institute melanoma clinical database in the world. It is an important national and international resource for research into ways of improving the management of patients with melanoma and other skin tumours.

This database has been funded by MIA, philanthropic donations and grants from National Health and Medical Research Council (NHMRC) and Cancer Institute NSW.

3 What do I have to do?

If you agree to contribute to this database, you will not be required to do anything other than sign the Participant Consent Form.

4 What does participation in this research involve?

Trained data managers will obtain relevant information from your medical record (held by your clinician) to store in the database. The database may also include information obtained from state and national registers of health information.

Occasionally, you may be contacted to confirm existing information, complete a relevant questionnaire, update your current follow-up status or be notified about other research projects which have ethical approval.

There are no costs associated with contributing to this database, nor will you be paid.

5 Do I have to take part?

Participation 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 database 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 or, your relationship with those treating you.

6 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 improved treatment of melanoma in the future.

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

There are no known risks or disadvantages of taking part in this project.

8 What if I withdraw from the Melanoma Research Database?

If you decide to withdraw from this database, please notify your clinician or one of the staff listed below. They will inform you if there are any special requirements linked to withdrawing.

If you do withdraw your consent, the data managers will not collect any further personal information about you and information that has already been collected will not be released for future research projects without your explicit consent.

9 Could this research database be stopped unexpectedly?

This database is a core element of the research of Melanoma Institute Australia. It is not anticipated that this will be stopped unexpectedly. MIA intends that any future shortfalls in funding will be avoided by their fundraising activities.

10 What happens when the Melanoma Research Database ends?

There is no planned end date for MRD.

Research that has used the Melanoma Research Database is typically published through scientific and medical journals and conferences. MIA also reports all its activities and research through its website, newsletters and through the media.

Part 2 How is the Melanoma Research Database being conducted?

11 What will happen to information about me?

By signing the consent form you consent to the data managers collecting and using relevant clinical information from your medical record held by your clinician(s). Any information obtained in connection with this research database that can identify you will remain confidential.

Identifiable information about you will be held indefinitely in the Melanoma Research Database which is located on secure computer servers at the Poche Centre, North Sydney. The database is overseen by the MIA Research Committee which includes clinicians, pathologists, medical scientists and senior data managers. The MIA Research Committee will review researcher applications and authorise the release of information to researchers.

In the database your health information will be allocated a number to protect your privacy. Your name will be recorded in connection with this number, but information about you will only be linked to your number. The information will always be treated confidentially, and only the database custodian, their assistants and authorised researchers will have access to it. Information released for research external to MIA will have identifying information removed before it is transferred.

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 database.

When information stored in MRD is used in research, the results that are published or presented in any forum information will be altered in such a way that you cannot be identified.

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

In accordance with relevant Australian and/or NSW privacy and other relevant laws, you have the right to request access to the information collected and stored in MRD about you. You also have the right to request that any information with which you disagree be corrected. Please contact your clinician or the staff listed below if you would like to access your information.

Any information obtained for the purpose of this research database and for the future research described in Section 11 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 questions or you wish to discuss the use of information about you, you should contact the MIA CEO on 02 9911 7200 or research@melanoma.org.au, or your MIA clinician.

13 Who is organising and funding this database?

MRD is managed by Melanoma Institute Australia, funded through research grants and philanthropic donations. Knowledge acquired through research involving information stored in MRD may lead to discoveries that are of commercial value to Melanoma Institute Australia, researchers or their institutions. There would be no financial benefit to you or your family from these discoveries.

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 Sydney Local Health District (RPAH zone).
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

If you want any further information concerning this project you can contact any of the following people:

Contact person

Name	*Richard Scolyer*
Position	*Co-Medical Director*
Telephone	*9911 7200*
Email	*research@melanoma.org.au*

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

Site contact person

Name	*Robyn Saw*
Position	*Head of Melanoma and Surgical Oncology*
Telephone	*9515 5072*
Email	*Smso@melanoma.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

Protocol Number	*X15-0311*
Reviewing HREC name	*Sydney Local Health District (RPAH Zone)*
HREC Executive Officer	*Patricia Plenge*
Telephone	*9515 6766*
Email	*SLHD-RPAEthics@health.nsw.gov.au*

Consent Form - *Adult providing own consent*

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Short Title	Melanoma Research Database
Protocol Number	2.0
Project Sponsor	Melanoma Institute Australia
Principal Investigator	Professor Richard Scolyer
Location	*Royal Prince Alfred Hospital*

Family Name	
Given Names	
D.O.B _____/_____/_____	☐ Male ☐ Female
Address	
COMPLETE ALL DETAILS or AFFIX PATIENT LABEL HERE	

Declaration by Participant

I confirm that I agree to all of the following:

- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand the purposes, procedures and risks of the Melanoma Research Database.
- I give my consent for my health information to be collected, stored indefinitely and to be used in ethically approved health and medical research.
- I understand that I am free to withdraw at any time 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, or state and national registers of health information to release information to Melanoma Institute Australia concerning my condition and treatment for the purposes of this research database. I understand that such information will remain confidential.

_____ Participant Name	_____/_____/_____ Date of Birth	_____ Signature	_____/_____/_____ Date
_____ Witness Name (to Participant's Signature)		_____ Signature	_____/_____/_____ Date
_____ Study Doctor / Researcher: Name, Designation		_____ Signature	_____/_____/_____ Date