QSKIN II

PARTICIPANT INFORMATION

We are conducting a medical research study to collect information on how a person's "genetic make-up" influences their risk of developing skin cancer and other medical conditions. You have been invited to take part in this study and this web page will tell you what the study is all about. We are seeking people 18 years of age and over, and who reside in Australia to participate in the study. Before you decide to take part in the study we want you to have all the facts. Please read this information carefully. Your participation is voluntary and there will be no cost to you if you do not wish to take part. Choosing not to take part in this study will not affect your future medical care in any way. If you have any questions please contact a member of the team on

1800 222 600 or email **qskin@qimrberghofer.edu.au**

If you agree to take part in the study we will ask you to fill out a survey form. You will also be asked to provide a saliva sample.

1. WHO IS CONDUCTING THE STUDY?

The study is being conducted by doctors and scientists at the QIMR Berghofer Medical Research Institute, led by Prof David Whiteman and Dr Catherine Olsen. The study is funded by a $3.2 million research grant from the National Health and Medical Research Council (NHMRC) of Australia. The study has been approved by the Research Ethics Committees of these institutions in accordance with the guidelines of the NHMRC.

2. WHY DO YOU WANT ME TO TAKE PART?

Australians have the highest rates of skin cancer in the world. Each year more than 400,000 Australians are treated for skin cancer. With better knowledge of the causes, we can work towards better methods for preventing and treating these cancers. The ***QSkin Sun and Health Study*** began in 2010 and is documenting the skin cancer experience of nearly 45,000 people, making it the largest study of its type in the world. A key objective of the study is to find the genes that increase or decrease a person's risk of getting skin cancer. Genetic studies require very large numbers of participants to have enough statistical power to find the important genes. We therefore wish to invite more people to take part in this research. These samples will enable us to see how genes vary for different people, and how they might be related to risk of skin cancer. If you take part, you may help to develop new treatments to prevent or treat skin cancers or other medical conditions.

3. WHAT DOES BEING IN THE STUDY INVOLVE?

Participation in this study is voluntary. If you agree to take part, being in the study will involve the following steps:

(1) completing a survey online: this will be about your general health, lifestyle and well-being (it will take about 20 minutes to complete)

(2) the QSkin team following health and other records relating to you, including hospital records, cancer records, death records and other health-related records

(3) being contacted in the future to provide information on changes to my health and lifestyle. You may also be asked to provide further information including survey responses or biological samples; your participation in any of these would be completely voluntary

(4) providing a small saliva sample (2 mL) (instructions on how to provide the saliva sample

are included with the collection tube). **You should not eat, drink, smoke or chew gum for 30 minutes before providing the sample**. About half a teaspoon of saliva is needed. This typically takes about 5 minutes.

(5) If you agree, you will be asked to fill out a consent form authorising the study access to your complete Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data as outlined in the consent form. Medicare collects information on your doctor visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to the Department of Human Services who holds this information confidentially. Consent to access your MBS/PBS claims information is completely separate from consent for the rest of the study (online survey and saliva sample). You can participate in the other parts of the study without consenting to the MBS/PBS component.

There may be no direct benefit to you from taking part in the study however the findings of the study are likely to help people who have skin cancer in the future. There will be no cost to you and if you do not want to take part this will not affect your future medical care in any way.

4. IF I GIVE A SALIVA SAMPLE, WHAT WILL IT BE USED FOR?

We will use your saliva sample to study the genes that might change the risk of skin cancer or affect how skin cancer responds to treatment (see section on Genetic Research at the end of this document). It is possible that genes might make someone more or less likely to get skin cancer. Until this research gets done, nobody knows whether or not this is true. We may keep some of your sample indefinitely for future studies to answer new research questions about other health conditions (see the section on ‘Future Research’ below).

Your genetic information and some of survey information (but not your name or other personal details) may eventually be put into an international genetics data repository. Information in the database will be available only to researchers from around the world who are approved to study how genes cause a variety of health conditions. These scientists will not know your name or other personal information we learn about you.

Any PBS/MBS data you consent to provide will be used for the purposes of this study only. It cannot be used for any other future research studies.

5. HOW IS MY PRIVACY PROTECTED?

When you fill out a survey or donate a sample of saliva to this study we will make every effort to protect your privacy.

- The QSkin II Study is bound by Commonwealth and State privacy legislation, including the Privacy Act 1988 (Commonwealth) and the Information Privacy Act 2009 (QLD). In addition, the study must adhere to the guidelines of the National Health and Medical Research Council of Australia, and is also accountable to the QIMR Berghofer Medical Research Institute Human Research Ethics Committee.
- All your surveys and samples will be stored securely in such a way that they cannot immediately be identified as having come from you. They will be labelled with a unique identifier so that they do not get confused with surveys or samples from someone else.
- Any identifying information (your full name, address etc) will be stored separately from the samples and information you provide, on secure QIMR Berghofer Servers. Access to this identifying information is restricted to a small number of senior members of the study team.

- Your study records may be viewed for the purposes of source data auditing by members of the Ethics Committee.
- No information that could be used to identify you or your family will be included in any report on the results of the study.

6. CAN I WITHDRAW FROM THE STUDY?

You may withdraw from the study at any time and this will in no way affect your medical treatment in the future. If you decide now that your saliva sample can be kept for research, you can still change your mind later. Just contact us and let us know that you do not want us to use your samples. Any remaining saliva or samples that have not been used will then be destroyed, however it may occasionally not be possible to destroy material that has already been processed.

If you withdraw from the study any PBS/MBS data you consent to provide will be deleted from our computer systems. However, any research findings associated with your MBS/PBS data will not be able to be destroyed or recalled. If you withdraw before we request PBS/MBS data, no data will be supplied.

7. WILL I FIND OUT THE FINDINGS OF THE RESEARCH USING MY SALIVA?

The results of research done with your saliva are not likely to be available in the immediate future. This is because research can take a long time and must use samples from many people before the findings are known. We will not be able to give you the individual results from your samples. Your information will be analysed in combination with information from other participants in this study. The nature of the research means that the data is de-identified prior to analysis, and only results of a global (not individual) nature will be produced. Everyone who takes part in the *QSkin Study* is sent regular newsletters to let you know in general, how the study is going. You are also welcome to contact the Study Team at any time if you have any questions about the study.

8. FUTURE RESEARCH USING YOUR SAMPLES AND DATA

After we have finished this particular study we will keep the information and remaining samples that you give us indefinitely. This is because they are very valuable and may help us answer other new health questions in the future. In the future we may match your personal data against other registers and we will use your samples for future genetic studies. Your information and samples will be stored at QIMR Berghofer and only authorised staff will have access to them. They will be identified only by your unique study number and will be stored separately from your name and other identifying information.

We will ask if you are happy for us or other approved scientists to use your information and samples for future research studies (see also Section 9 on Genetic Research). **Any extra studies that use your samples would have to be approved by the relevant scientific and ethics committees. Any information or material we give to researchers would be identified by a code only so it would not be possible for them to identify you.** There will be no additional risks to you if you give permission for us to use your data and samples in this way. If you do give consent for this you will not receive notice of future use of your information or samples. If you give us permission to use your material for other studies now you can still change your mind at any time. Just call or write to us to let us know.

Any PBS/MBS data you consent to provide will be used for the purposes of this study only. It cannot be used for any other future research studies. The original records supplied to the research team (including information provided in the consent form) will be deleted from our computer systems seven years after the publication of the final project report, or ten years from the date of supply, whichever is sooner. However, any research findings associated with your MBS/PBS data will not be able to be destroyed or recalled.

There is a chance that information derived from the samples that you are donating under this study may, in the future, have some commercial value, for example if they lead to the development of a commercial product. You will not be compensated for your participation in the study or for any future value that the sample you have given may be found to have. However, it is our intention that if money is generated as a result of research using your samples then some will be put into a special fund to be used for future research into medical disorders.

9. GENETIC RESEARCH

People respond differently to things they come into contact with such as sunlight, alcohol, foods and medications. This is partly because people have different genes. Some genes may make people more or less likely to become ill when they come into contact with particular factors. We are trying to find out which genes these are, in the hope that this will lead to new treatments that act in the same way as the ‘good’ genes.

How do we get a sample of your genes?

DNA is the genetic molecule of life and it carries the hereditary information that underlies the physical and behavioural characteristics of all living things. DNA makes up genes, and genes are arranged into larger structures called chromosomes.

We can obtain a sample of DNA from your saliva. When your sample arrives at our laboratory, we extract DNA from it. Scientists use centrifuges and chemicals to purify the cells and to extract purified DNA from these cells. The DNA will then be screened to look for variations in the genetic code. By comparing thousands of samples, we can determine whether variants of certain genes are more or less common in people with skin cancer, for example. Similar approaches can be used to find genes associated with other human conditions.

Are there any risks if I participate?

There is no risk of harm to you or others in providing the saliva sample.

Currently in Australia, genetic research does not affect your ability to obtain private health insurance (although there may be a waiting period for pre-existing conditions). It is, however, possible that in the future the fact that you have taken part in a study involving genetics might affect you or your family if you want to take out a new health, disability or life insurance policy. We will not pass any information about you to anyone, including your family members, without your written permission unless lawfully obliged to. If you would like more information about genetic research and health insurance please call the QSkin Helpline on 1800-222-600**.**

10. WHAT IF I HAVE MORE QUESTIONS OR A COMPLAINT ABOUT THE STUDY?

If you have any questions about the study, please call our *free* **Study Helpline** on **1800 222 600** or email **qskin@qimrberghofer.edu.au**

Or phone any of the following people:

A/Prof Catherine Olsen (Project Manager)	(07) 3362 0224
Prof David Whiteman (Chief Investigator)	(07) 3362 0279

ETHICS COMMITTEE CONTACT AT THE QIMR BERGHOFER MEDICAL RESEARCH INSTITUTE

If you have a complaint or would like to speak to someone who is not involved in the study, you can contact:

Sashika Naidoo Regulatory Affairs QIMR	Tel: (07) 3362 0433 Fax: (07) 3362 0109 Email : Sashika.Naidoo@qimrberghofer.edu.au

If you do not wish to participate, thank you for your time. You are not required to respond in any way. You may close the browser window to exit.

I have read this information sheet and have understood it.

Save and Continue

Are you willing to provide a saliva sample for this study?

- We will send you a specialized collection container for your sample
- You will be asked to return this sample via Australia Post to our laboratory, at no cost to you.

○ Yes
○ No

<if yes, proceed to Consent Form>
<if no, redirect to Refusal Page>

Save and Continue

QSkin II Participant Consent Form

PART A. Consent for the QSkin II Study

☐ **I hereby freely consent to** take part in the *QSkin II Study* as described in the Information Brochure, including completing a brief survey and providing a small saliva sample (2 mL).

In giving my consent I confirm that:

- I have read, or have had read to me, and understand the *QSkin II* ***Study Information Sheet***.
- I have had a chance to ask questions and I am satisfied with the answers I have received.
- I understand that I can withdraw my consent to participate in the *QSkin II Study* at any time.
- I understand that the research team will not reveal my identity and personal details if information about the *QSkin II Study* is published or presented in any medium.
- There will be no cost, nor any financial benefit to me for participating in the study.
- I may be approached again to participate in future studies but I am under no obligation to do so.

PART B. Consent for future use of biological samples and data

☐ **I also consent to** my data (MBS and PBS data excluded) and samples being used for future research and made available to other scientists for approved research studies.

I understand that my questionnaires and samples will be stored at the QIMR Berghofer Medical Research Institute and that all studies using my samples and data will have to be approved by the relevant Human Research Ethics Committees.

- I understand that I will not be notified about future use of my samples and data (excluding MBS and PBS) and that I will retain no rights to the material I donate to the study or anything that is derived from it.
- All studies using my samples will have to conform with the ethical and scientific principles set out by the National Health and Medical Research Council of Australia, the Privacy Act 1988 and the Guidelines approved under section 95A of the Privacy Act (2001).
- If at any time I decide that I no longer wish to participate in the study, my samples will be discarded upon my written request to the Study Investigators. This will not affect my future medical treatment.

Save and Continue

PART C. Medicare and Pharmaceutical Benefits Scheme (PBS) Claims Consent

Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) Claims Information

On the next page, you will be asked to fill out a consent form authorising the researchers to access your complete Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data as outlined in the consent form. Medicare collects information on your medical visits and procedures, and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to the Department of Human Services which holds this information confidentially.

If you do provide your consent for access, we will request the following information from the Department of Human Services:

Medicare (MBS)

- Date of service (Date that the provider performed the service)
- MBS Item number (Item numbers as per the Medicare Benefits Schedule)
- MBS Item description (describes the service as per the Medicare Benefits Schedule)
- Provider charge (dollar amount the provider charged for the service)
- Schedule fee (Fee listed in the Medicare Benefits Schedule)
- Benefit paid (Medicare benefit paid to the claimant)
- Patient out of pocket (dollar amount the patient is out of pocket)
- Bill type (how the Medicare benefit was claimed e.g. bulk billing, cash)
- Scrambled ordering provider number (a number unique to the provider who referred the service, but scrambled so that the doctor cannot be identified)
- Scrambled rendering provider number (a number unique to the doctor who provided the service, but scrambled so that the doctor cannot be identified)
- Date of referral (date of referral or request for service by a provider)
- Rendering provider postcode (postcode of the service provider’s practice location)
- Ordering provider postcode (postcode of the referring provider’s practice location
- Hospital Indicator (Indication of whether or not the service was provided as a private patient in a public hospital, not the name of the hospital)
- Item category (categorisation of services according to Medicare groupings)

A sample of the information that may be included in your Medicare claims history:

Date of service	Item number	Item description	Provider charge	Schedule Fee	Benefit paid	Patient out of pocket	Bill type
20/04/09	00023	Level B consultation	$38.30	$34.30	$34.30	$4.00	Cash
22/06/09	11700	ECG	$29.50	$29.50	$29.50		Bulk Bill

Scrambled ordering Provider number*	Scrambled rendering Provider number*	Date of referral	Rendering Provider postcode	Ordering Provider postcode	Hospital indicator	Item category
	999999A		2300		N	1
999999A	999999A	20/04/09	2300	2302	N	2

** Scrambled Provider number refers to a unique scrambled provider number identifying the doctor who provided/referred the service. Generally, each individual provider number will be scrambled and the identity of that provider will not be disclosed.*

Pharmaceutical Benefits Scheme (PBS)

- Date of supply (Date the prescription was supplied by the pharmacy)
- Date of prescribing (Date that the prescription was prescribed by a Medical Practitioner to a patient)
- PBS item code (items number reflected in the Pharmaceutical Benefits Scheme)
- PBS item description (the item description as noted in the Pharmaceutical Benefits Scheme Book)
- Patient category (concessional status of the patient at time of supply)
- Patient contribution (dollar amount paid by the patient)
- Net benefit (dollar amount paid to the pharmacy by Department of Human Services)
- Scrambled prescriber number (number unique to the doctor who prescribed the PBS item, but scrambled so that the doctor cannot be identified)
- Pharmacy postcode (postcode of the pharmacy where the prescription was dispensed)
- Form category (Original or repeat prescription)
- ATC Code (the code allocated by the World Health Organisation Collaborating Centre for Drug Statistics Methodology)
- ATC Name (the group the drug falls under in the Anatomical Therapeutic Chemical (ATC) classification system)

A sample of the information that may be included in your PBS claims history:

Date of supply	**Date of prescribing**	**PBS item code**	**Item description**	**Patient category**	**Patient contribution (this includes under copayment amounts)**	**Net Benefit (this includes under copayment amounts)**	**Scrambled Prescriber number***	**Pharmacy postcode**
06/03/09	01/03/09	03133X	Oxazepham Tablet 30 mg	Concessional Ordinary	$5.30	$25.55	9999999	2560
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	General Ordinary	$30.85		9999999	2530

Form Category	**ATC Code**	**ATC Name**
Original	N05 B A 04	Oxazepam
Repeat	N05 B A 01	Diazepam

** Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.*

Consent for this section is not required for overall study participation. If you do not wish to provide consent for Medicare and PBS data access, simply select "I do not wish to consent to release Medicare and PBS Claims Information" below. You will still be eligible to participate in all other aspects of the study.

Information Supplied by the Australian Government Department of Human Services

APP 5 – PRIVACY NOTICE

Your personal information is protected by law, including the Privacy Act 1988, and is collected by the Australian Government Department of Human Services. The collection of your personal information by the department is necessary for administering requests for statistical and other data.

Your information may be used by the department or given to other parties for the purposes of research, investigation or where you have agreed or it is required or authorised by law.
You can get more information about the way in which the Department of Human Services will manage your personal information, including our privacy policy at humanservices.gov.au/privacy or by requesting a copy from the department.

○ Proceed to consent form for Medicare and PBS claims information

- ○ I do not wish to consent to release Medicare and PBS claims information. Proceed directly to the survey

Save and Continue

Consent to release of Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) claims information for the purposes of the QSkin II Study.

Important Information

Complete this form to request the release of personal Medicare claims information and PBS claims information to the QSkin II Study. Incomplete forms may result in the study not being provided with your information.

By indicating my consent, I acknowledge that I have been fully informed and have been provided with information about this study. I have been given an opportunity to ask questions and understand the possibilities of disclosures of my personal information.

Title:

Family name:

First given name:

Other given names:

Date of birth:

Residential address:

Postal address:

Medicare card number (first nine digits, no spaces):

☐ I declare the information on this form is true and correct

Please indicate below your intent:

☐ I authorise the Department of Human Services to provide BOTH my Medicare (MBS) and Pharmaceutical Benefits Scheme (PBS) claims history for the period *<today's date>* to *<31/12/2030>* to The QSkin II Study

OR

☐ I authorise the Department of Human Services to provide ONLY my Medicare (MBS) claims history for the period *<today's date>* to *<31/12/2030>* to The QSkin II Study

OR

☐ I authorise the Department of Human Services to provide ONLY my Pharmaceutical Benefits Scheme (PBS) claims history for the period *<today's date>* to *<31/12/2030>* to The QSkin II Study

Save and Continue

Please provide your contact details. We will store these details and use them if we need to contact you in the future about the study.

Title:

Family name:

First given name:

Other given names:

Date of birth:

Sex:

Residential address:

Postal address:

<Pre-populate the relevant fields if participant has provided these in the PBS/MBS consent section>

Email:

Phone number:

Sometimes we find that people have moved when we try to contact them again. It would be very helpful if you could give us the contact details of someone close to you (such as a relative or friend) who we could contact if we are unable to reach you. We would only get in touch with that person if we were unable to contact you directly and we would need to tell them our reason for contacting you. Please leave this section black if you do not wish to provide these details:

Full name of contact person:

Residential address of contact person:

Phone number of contact person:

Email address of contact person:

Save and continue to complete the survey