

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