INFORMATION FOR VOLUNTEERS FOR STUDY PARTICIPANTS

Understanding the biological responses to sun exposure

QUT RESEARCHERS: Dr Elke Hacker, Research Fellow
QIMR RESEARCHERS: Professor Nicholas Hayward

You are invited to take part in this research study. Participation in this study is voluntary. This Participant consent pack contains detailed information about the research study. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Participant Information Sheet carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the project with a relative or friend or your local health worker. Feel free to do this.

Once you understand what the project is about and you decide that you will take part, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to take part in the research study.

You will be given a copy of the Information Sheet and Consent Form to keep as a record.

Why is this study being undertaken?

Skin cancer is the most common cancer in the Australian population, and incidence rates continue to rise. This study will generate the early evidence for determining safe UVR exposure thresholds and provide data for further research.

Who is conducting the study?

Doctors and scientists based at Queensland University of Technology (QUT) and QIMR Berghofer.

If I decide to take part, what do I have to do?

Your involvement would include two visits to QUT:

- **Visit 1:** Filling in a survey form asking about your type of skin, your medical history and sun exposure behaviour.
- Collection of a saliva sample
- One biopsy of a non-UVR exposed site and one immediately following UV exposure on your lower back.
- Exposing a row of five square areas of skin on your **back** (each with an area of 1cm^2) to a low dose of ultraviolet light (similar to natural sunlight). The exposure will be similar to approximately 15, 30, 40 minutes in the sun at 7am in Brisbane during summer just enough to cause very faint redness- , which is called your Minimal Erythemal Dose (MED). This UV exposure is less than 1 MED. This is a 1.5 hour visit.
- **Visit 2:** On a subsequent visit the next day you will have 3 x skin biopsies on the lower back that was exposed to UV the previous day. Each biopsy will be only 1mm diameter and will be taken under local anaesthetic. This is a 1 hour visit.

Who can participate?

We are looking for fair skin individuals with skin type I - III aged 18 years of age and over.

Individuals are excluded from participating if they have a history of allergy or adverse reactions to local anaesthetics or any related drug. A medical history will be recorded to ensure you are not taking any medications, which may cause photosensitivity (you are sensitive to light) or known or suspected to reduce, inflammation immunity or healing (e.g. corticosteroids). Participants must not be on blood thinning medication. Participants are also excluded if they are pregnant, have a history of skin cancer, keloid scarring, heart disease, liver disease, kidney disease, diabetes of any type, or any significant gastrointestinal disorder.

Please contact the research team if you are unsure if you meet these criteria.

Participants will be asked questions surrounding ethnicity because the response of skin cells to UV radiation varies based on genetic variations.

What happens to these samples?

Skin samples will be examined under the microscope looking at the number of pigment cells and the way in which these cells express different proteins in response to low levels of UV light. Your sample will be stored securely and will be used only by this research team.

DNA will be collected from you by a saliva sample to look for genes thought to be related to skin cells responses to sunlight (see section 'Genetic Testing" on page 4). You will be asked not to consume foods, drinks, cigarettes or chewing gum 30 minutes before the saliva sample.

Can I Withdraw from the Study?

Your participation is completely voluntary. Your decision whether to take part in no way affects your future medical treatment. If you do decide to take part, you are free to withdraw from the study at any time. If you decide to withdraw your information, survey data, tissues and DNA can be kept for research or you can contact us and let us know that you do not want us to use your samples. Any tissue and DNA that remains will then be destroyed.

Will I find out the Results of Research using my Samples?

The results of research done with your tissue or DNA will not be available in the immediate future. This is because research projects take a long time and have to use tissue samples from many people before the results are known. You are also welcome to contact the Study Team at any time if you have any questions about the study.

Are there any benefits to taking part in this study?

It is expected that this research project will not directly benefit you. However, the results of this research may benefit future skin cancer programs.

Will I be paid for my participation?

Each person taking part will be provided for time and travel expenses at the completion of all biopsies with $100 cash. Participants will be offered free parking at QUT, or have the option of free taxi vouchers to and from QUT for both visits.

What about my privacy?

Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of this research project. It will only be disclosed with your permission except as required by law.

When results of the study are published in scientific journals, or presented at scientific meetings, it will be done in a way that individual participants cannot be identified. We will follow the guidelines to protect your privacy that have been developed by the State and Federal Governments.

Future Research Using Your Samples

It is not anticipated there will be any of your tissue samples left after use in this study. If at the conclusion of the study there are still tissue samples available future access will be restricted to this research group on the current topic only. After we have finished this study we will keep the information and remaining samples that you give us indefinitely. We may also contact you again to ask you to take part in a follow-up study but you will be under **no obligation** to do so. Any extra studies that use your samples will have to be approved by the Ethics Committee at QUT. Any information or material given to researchers will be identified by a code only so it will not be possible for them to identify you. You will not receive any notice of future uses of your information or samples.

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 skin cancer.

Genetic Testing

People respond differently to things they come into contact with such as sunlight, alcohol, foods and medications. This is partly due to their genes. For example, some genes may make people more or less likely to develop freckles when they go out in the sun. Other genes might affect the response of pigment cells to sunlight. We are trying to find out which genes these are, hoping that this will lead to new treatments methods to protect against skin cancers.

We would greatly appreciate your participation in the genetic part of the study. However this decision is entirely your own and you do not have to give us any explanation if you do not want to take part.

How will you get a sample of my genes?

DNA is the body's genetic material, which 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.

A sample of your DNA will be collected from you by a saliva sample. When your sample arrives at our laboratory, we extract DNA from it. Scientists use centrifuges and chemicals to purify the cells and extract DNA.

The purified DNA will then be screened to look for several genes which are thought to be related to sunlight and melanoma.

What genetic information will this study find out about me?

This study is examining the MC1R gene, which is a gene involved in pigmentation and is associated with red-hair and freckles. Further genetic markers associated with the proliferated response of melanocytes following UVR may be identified during this study. It is unlikely that these findings will impact the clinical treatment or health insurance of you the participant (see explanation below).

What are the risks of Genetic Research?

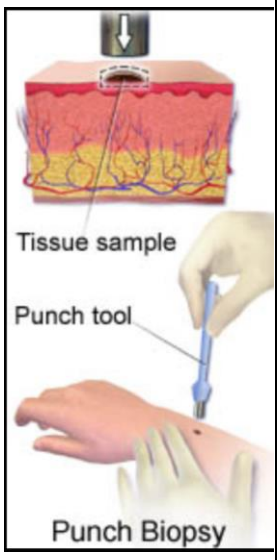
It is important to separate **genetic research** ("making a voluntary donation to a medical research study for no direct benefit to the donor") from **genetic testing** ("providing a sample on the professional advice of a doctor or genetic counsellor to test for specific genes of direct significance to the patient"). You are being invited to take part in genetic research; you are **not** being asked to undergo genetic testing.

Currently in Australia, genetic testing does not affect your ability to obtain private health insurance (although there may be a waiting period for pre-existing conditions), and neither does taking part in genetic research. It is, however, possible that in the future the fact that you have taken part in a study involving genetics may affect you or your family if you want to take out a new health, disability or life insurance policy. **We will not pass on this information** about you to anyone, including your family, without your written permission unless lawfully obliged to.

What are the risks of taking part in this Study?

UV exposure:
You will be exposed to a small amount of ultraviolet light on the skin of your back (about the same as 5 minutes in the sun before 8am in Brisbane summer sun). You may develop mild **sunburn** at these sites.

Biopsies:
There is a risk of **bleeding** following the biopsy, although we would always stop this before you are sent home.



(If you are taking any medications which might stop your blood clotting, then we might decide to exclude you from taking part in the study).

Some people feel **minor pain** and **discomfort** following a skin biopsy.

An uncommon complication is **infection** of the biopsy site. This can be treated with antibiotics if required.

Some people may develop **scarring** at the biopsy site. Finally, a very small number of people may develop **allergies** to local anaesthetic agents, which may be **life-threatening**.

(If you have a history of allergy to anaesthetic agents, then we will stop you from taking part).

What if something happens to me?

In the very unlikely event that you require any medical treatment occurring as a result of taking part in this study, your treatment costs will be covered by the study. Our clinic team will provide medical care. The study is covered by no-fault insurance that will compensate any injury arising as a direct result of taking part in this study.

Where can I get further information?

We would be happy to answer any queries or discuss any problems that you may have.

Please contact us at the telephone numbers listed below.

Dr Elke Hacker, QUT
Work: 07 3138 9674
Email: skntec@qut.edu.au

If you have a complaint:

QUT is committed to research integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the research project you may contact the QUT Research Ethics Advisory Team on 07 3138 5123 or email humanethics@qut.edu.au.

The QUT Research Ethics Advisory Team is not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

Study Timetable

VISIT	What will happen?	Why is this done?
Visit 1	• You will be asked to complete a consent form and survey	To gather information about your sun exposure behaviour and skin type as well as check for any medical reasons why you shouldn't participate in this study.
	• Collect saliva sample	To collect DNA
	• We will conduct one biopsy on non-UVR exposed skin and one following UV exposure.	Each person's skin reacts differently to sunlight. We want to assess how <u>your</u> skin reacts without UV exposure.
	• We will expose the skin on your back to a low dose of UV radiation below UV Index 3	Each person's skin reacts differently to sunlight. We want to work out how <u>your</u> skin reacts to a given dose of UV radiation.
Visit 2	• We will look at the skin on your back to see how red it is. We will take **3** skin biopsies on the back.	To determine how you skin recovers 1 day after sun exposure

CONSENT FORM FOR VOLUNTEERS FOR STUDY PARTICIPANTS

Understanding the biological responses to sun exposure

I, _____ _____
(FIRST NAME) (FAMILY NAME)

volunteer to be a subject in the above-named study.

By signing this form, I agree with the following:

1. I will visit the clinic for all testing.
2. The skin of my back will be exposed to solar simulator ultraviolet radiation. The dose is generated from artificial lamps and is similar to exposure to 5-10 minutes of sunlight in Brisbane in summer before 8am.
3. I will have 5 skin biopsy samples taken, the details of which have been explained to me.
4. I will have my DNA collected from a saliva sample.
5. I have had the opportunity to ask questions about the study and have received satisfactory answers.
6. I have been told that this work is experimental research. I acknowledge that I have read the information for volunteers provided.
7. I agree to provide a DNA sample for genotype testing.
8. I have no past history of allergy or adverse reactions to local anaesthetics or any related drug.
9. I have no past history of keloid scarring.
10. I have never had heart disease, liver disease, kidney disease, diabetes of any type, or any significant gastrointestinal disorder.
11. Research data gathered from the study may be published provided that my name is not used.
12. I understand that I will be reimbursed for time and travel expenses to the value of $100.
13. I realize that I have the right to withdraw from the study at any stage. I also understand that the investigators have the right to terminate the study at any stage before completion if they believe this is in my best interests. In this case, I will still receive a thank you gift. This study has been approved by the QUT Human Research Ethics Committee (HREC) in accordance with the National Health and Medical Research Council's guidelines.
14. I am free to discuss my participation in this study with project staff (Principal Investigator Dr Elke Hacker, Telephone 07 3138 9674).
15. If you have any concerns and/or complaints about the study, you may contact the Human Research Advisory Team of the QUT HREC on 07 3138 5123.

☐ I give specific consent for use of the collected samples for this project alone.

OR

☐ I give extended consent for use of the collected samples for this project and related melanoma projects in the future.

☐ I would like to receive the study newsletter describing outcomes of this research (optional).

Signature of Volunteer: _____

Date: _____

Signature of study representative who conducted the informed consent discussion: _____

Date: _____