

Participant Information and Consent Form

Site: **MASTER VERSION**

Project Title: Australian Centre of Excellence in Melanoma Imaging & Diagnosis (ACEMID) Cohort Study

Principal Investigator: Prof H. Peter Soyer, University of Queensland, Brisbane

Site Principal Investigators: Prof H Peter Soyer, University of Queensland
Prof Pablo Fernandez-Penas, University of Sydney
A/Prof Victoria Mar, University of Monash

This Participant Information and Consent Form is 12 pages long. Please make sure you have all the pages.

1. Purpose and Background

Melanoma is Australia's national cancer and early detection of melanoma is vital for improved prognosis.

We aim to implement 15 x 3D total body photography machines across Australia for the monitoring of skin spots or moles and the early detection of skin cancer. The 3D total body photography machines enable imaging of all skin surfaces (except soles of feet, scalp and areas covered by clothing) to high levels of detail. This will significantly improve identification and tracking of skin spots or moles.

2. Your Consent

You have been invited to participate in a study that will use 3D total body photography to monitor skin spots or moles for the early detection of skin cancer.

This participant information form contains information about the research project and explains all the procedures involved. Knowing what is involved will help you decide if you wish to take part in the research. Please read this information carefully and ask any questions you may have about this study.

Your participation is voluntary

Your participation in this study is completely voluntary and there will be no cost to you. If you do not wish to take part in this study you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current and future medical care in any way.

Your withdrawal from the study

You are under no obligation to continue with the research study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons and you do not need to provide a reason.

You can withdraw from the study at any time by completing and signing the 'Participant Withdrawal of Consent Form'. This form is provided at the end of this document, and is to be completed by you and supplied to the research team if you choose to withdraw at a later date.

If you withdraw from the study, you will be able to choose whether the study will destroy or retain the information it has collected about you. You should only choose one of these options. Where both boxes are ticked in error or neither box is ticked, the study will destroy all information it has collected about you.

If you agree to take part, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you:

- understand the information;
- consent to take part in the research project;
- consent to have the tests that are described;
- consent to the use of your personal and health information as described.

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

3. What does participation in this research involve?

If you had expressed interest to participate or were referred to us by your medical practitioner, we will contact you to be assessed for your eligibility to be included in the study and to assess your melanoma risk factors. Participants will then be asked to attend one of 15 hospital facilities most convenient for the participant. At the first visit, a member of the study team will go through the participant information sheet and consent forms.

Once consent is obtained, we will ask participants to complete online questionnaires to collect information regarding demographics, sun protection behaviour, past sun exposure, personal and family skin cancer history and quality of life.

We will then image participants using the 3D total body photography system (see Figure 1 on page 3). Participants will need to be imaged in their underwear. The photography system consists of a panel of 92 cameras that instantaneously take an image, and then the software constructs a 3D model of your body. We then use a dermoscopic (magnified) camera that can capture highly detailed images of individual moles or spots of concern and link each one to their location on the body. The software allows us to map and monitor moles and skin spots over several visits to track their progress over time.

Based on the information provided in questionnaires, participants will be assigned to either the low/average risk, high risk or very high risk group based on your risk factors for melanoma.

Group	Frequency of study visits
Very high risk of melanoma	Participants are asked to return every 6 months for a period of 3 years to repeat 3D total body photography and dermoscopy.
High risk of melanoma	Participants are asked to return every 12 months for a period of 3 years to repeat 3D total body photography and dermoscopy.
Low/ or average risk of melanoma	Participants are asked to return every 24 months for a period of 3 years to repeat 3D total body photography and dermoscopy.

On the discretion of the dermatologist, you may be asked to come back sooner. We will also ask participants to complete follow-up questionnaires every 12-months.

We may request reports and relevant details of your diagnosis from medical officers, pathology laboratories and hospitals.

4. Optional Collection of Biological Samples

Part of our research involves investigating the genetic changes (mutations) that are associated with melanoma risk. We want to find out why certain mutations result in an increased risk to melanoma. To facilitate this research, we may approach participants and ask you to consider donating a saliva sample, skin to be biopsied, a blood sample and/or urine sample. These samples can then be used for additional analysis of gene products and proteins known to be involved in melanoma development and progression. Your decision whether to donate tissue, saliva, blood and/or urine not will not affect your eligibility for the study, you can still take part in the study and not donate any tissue, saliva, blood or urine.

During this study you may be referred back to your preferred dermatologist/or GP for skin biopsies or excisions. By signing this consent form, you consent to the study doctor and relevant research staff collecting pathology reports for this information from your treating doctor or relevant pathology laboratories for the purpose of this research. Any information obtained that can identify you will remain confidential. This information collected will be stored at the study site for a period of at least 15 years, after which time, the information will be destroyed.

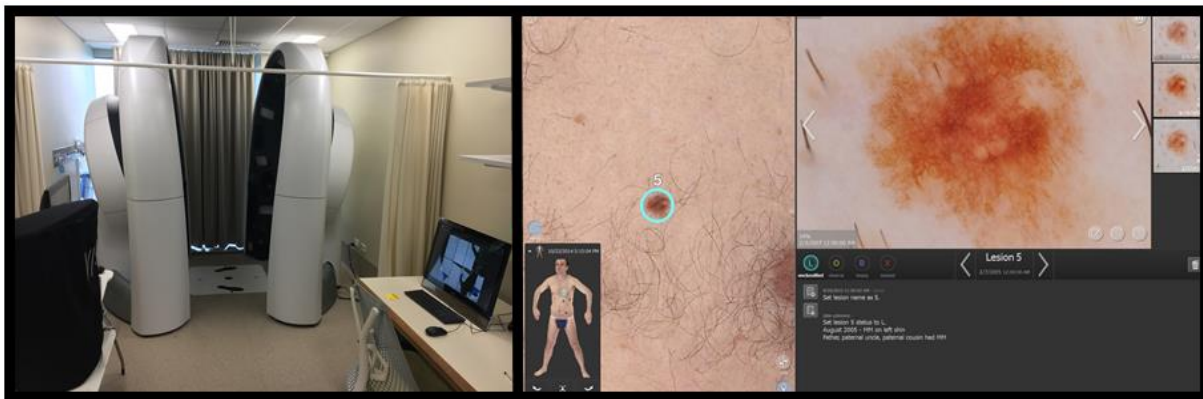


Figure 1: 3D total body photography machine (left image) and 3D avatar and pictures (right image) .

5. What will happen to my samples?

Saliva samples are used for genetic sequencing. We will be using techniques called whole-exome sequencing (WES), and whole-genome sequencing (WGS), which allows us to look at all your genes at once. We will use this information to see what genetic changes are associated with individuals that are high risk to melanoma.

We may ask some participants for a blood, urine and/or a tissue sample (skin biopsy). These samples would be used for laboratory tests to discover the reason why certain genetic changes may result in an increased risk to melanoma.

To protect your confidentiality, these samples are labelled with a code only (no personal details) before analysis in the laboratory, and only the study investigators will be able to connect the code with your personal details.

We also seek your consent for the use of the samples we collect for this study to be used for any future studies relevant to skin cancer or dermatological research that has received human ethical approval. If you wish to give this consent you should indicate this by ticking the appropriate boxes in the consent form at the end of this document.

You will retain the right to have your samples destroyed at any time by contacting the research team. If you decide to have your samples destroyed, any data or analyses that were done before the request cannot be removed. However, no additional analysis will be done on your samples, and all of your remaining samples

will be destroyed. The [insert institution] are responsible for organising the destruction of the samples at your request.

Please see section 11 of this form about withdrawal.

6. Use of images

3D total body photography images are used for later analysis by a trained researcher and/or dermatologist to characterise skin spots or moles and skin conditions as either benign (not harmful), or suspicious (requires removal, biopsy or treatment). As part of our research we will use these images to initiate the development of automated (computer) image analysis that has potential to be a valuable step towards the future detection of skin cancers, or other skin conditions, such as atopic dermatitis or psoriasis.

Images may be taken of pathology slides (if applicable) of biopsies taken during the trial for research purposes. Pathology images will be labelled with your study ID only and will be stored securely in the study database. Only the study investigators will be able to connect your study ID with your personal details. These images may also be used for future research to improve diagnostic accuracy, including training of computer algorithms.

7. Possible benefits

A dermatologist will view and examine images of your skin moles and spots at time intervals depending on your assigned melanoma risk group, and in the process may identify suspicious lesions for which you will be referred for recommended treatment.

All participants will have their personal risk factors assessed. Genetic testing may also find an increased risk to an unrelated condition. If this condition is treatable or preventable, you can select on your consent form whether you would like to learn this information.

Benefits of this research to the wider community include:

- Assisting researchers and clinicians to better understand the development and risk factors associated with melanoma and other skin cancers, as well as other common dermatological conditions.
- Developing new and improved methods of early detection and treatment of skin cancers and dermatological conditions.
- Developing new genetic and dermatological tests for skin cancers to identify at risk individuals, determine appropriate screening, and improve understanding of preventative measures.

Participation in this study does not replace the normal care and discussions that you may have had with your treating doctors.

We are unable to provide any monetary reimbursements for participation in this study.

8. Possible risks

As part of this study we plan to examine genes known to be associated with skin cancers, therefore we might find a defect in a gene which increases you or your family's risk for skin cancers. While doing this, we may coincidentally find a gene change that could be associated with an unrelated condition. If the gene change is related to a condition for which treatment or prevention is available based on the current medical knowledge at the time, you can specify on the consent form if you want to be contacted via writing to discuss the findings in more detail. Learning this information may be upsetting. This information could also affect your ability to get certain insurances in the future, and could be used against you in the work setting. Additionally, this information can have implications for the health of your family members and could impact family relationships. Individuals should weigh up the risks and benefits and decide whether or not to receive that

information. If we identify a gene change that is associated with a disorder that is currently untreatable and unpreventable, we will not contact you about this information.

There may be additional unforeseen risks or side effects which are unknown at this time.

9. Disclosure of results

If you agree to be contacted and we identify a genetic defect associated with an increased risk for skin cancers or an unrelated condition which is currently treatable or preventable, we will contact you in writing via mail/email to offer you the opportunity to arrange a face to face appointment with a member of the research team and a genetic counsellor to discuss the findings. Based on your consent at the time we will also contact your GP on your behalf to arrange referrals to appropriate specialists such as clinical geneticist or dermatologist. You may also be required to repeat the testing in a clinical setting.

10. Storage, retention and destruction of your information

All data will be stored in secure locations in either electronic or paper format. The data from this study will be kept for at least 15 years from the end of the study or last publication, after which it will be destroyed under security.

The imaging data will be stored indefinitely in a highly secure study database that meets national standards for data protection and privacy. Information about your participation in this study will be recorded in your health records.

Participant survey data will be stored using REDCap data management software, hosted by Monash University, Melbourne, Australia.

The samples (such as tissue, saliva, urine and blood) will be used for laboratory research and stored indefinitely at one or more secure, expert central laboratories, located at the *[insert institution]*, or until they are used up.

11. Privacy and confidentiality

All personal information obtained throughout the study, including physical examinations/imaging and the genetic or whole genome sequence will only be accessible in its identifiable form by the chief investigators or study coordinator. No identifiable information will be used in publication of the results.

Recently, some scientific journals in which human genomic and medical information is published have placed requirements for researchers to upload de-identified research data and/or the primary genetic data into designated databases before allowing the publication of study results. If this requirement is made upon us in the publication of our results, we may be required to release part of your genetic data from this study into electronic archiving database. Access to such databases, in which the results of many studies are combined, is stringently controlled in that they are managed by their own Human Ethics Research Committees. Any third party that wishes to access this information will need to first apply through the database Committee. The storage of this genetic data will in no way be identifiable to you. It will not include any of your identifying information, and will only contain the data that we have recognized as different to the reference human genome. It will not be your whole genome sequence, rather just a tabulation of the genetic differences when matched to the reference database sequence.

It is possible that there may be 'downstream' commercial use of some of the data from this research. However, all information which could potentially identify you will be removed before sharing with a company. Biological samples, such as tissue, saliva, urine and blood will not be shared with commercial companies. Some complete 3D total body image files taken during the study may be shared with companies

such as the manufacturer of the VECTRA 3D total body photography system. The manufacturer is Canfield Imaging Systems, located in New Jersey, USA. Sharing the images with companies such as Canfield will allow the research team to further develop image analysis software and possibly also fully or partially automate image analysis. This work may lead to an improved software for the total body photography system. All images will be kept strictly confidential and used only for the purpose of this project. It is possible that the *University of Queensland, Monash University or University of Sydney* may receive financial benefit from sharing the images and associated de-identified data with companies. This may be indirectly, through additional funded research or directly, as a result of licence fee payments or an equity deal or new discoveries. Under the latter circumstances, it is possible that this revenue may be shared with eligible University staff in a manner consistent with the University policy on Intellectual Property.

Optional: We also would like to include some images in publications and presentations of this study in the future. Any images used will not be identifiable (your face will not be included). You are asked whether you give your consent to the possible inclusion of your non-identifiable skin images in publications and presentations (optional). We will also ask whether you consent for your de-identified skin images to be used freely for various research studies including open access databases to benefit further research. There is a separate consent form where you can indicate if you will provide your consent for this optional component.

12. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you are not obliged to do so. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

13. Is this research project approved?

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2018) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been reviewed by the Human Research Ethics Committee of Metro South Health and *University of Queensland*.

14. Further Information and complaints

If you require further information or if you have any problems concerning this project you can contact the principal researchers or your State Manager:

<p>Principal Investigator Prof H Peter Soyer University of Queensland Tel: 07 3443 8017 acemid@uq.edu.au</p>	<p>Principal Investigator Prof Pablo Fernandez-Penas University of Sydney Tel: 02 8890 9767 Pablo.fernandezpenas@sydney.edu.au</p>	<p>Principal Investigator A/Prof Victoria Mar Monash University Tel: 03 9903 0724 victoria.mar@monash.edu.au</p>
<p>Queensland State Manager University of Queensland Dr Uyen Koh Tel: (07) 3443 8019 u.koh@uq.edu.au</p>	<p>New South Wales State Manager University of Sydney Ms Grace Kwaan Tel: (02) 8627 3773 acemid.project@sydney.edu.au</p>	<p>Victoria State Manager Monash University Dr Maithili Sashindranath Tel: (03) 9903 0724 acemid@monash.edu</p>

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

Metro South Hospital and Health Service Human Research Ethics Committee

HREC Coordinator

Tel: 07 3443 8047

ethicsresearch.PAH@health.qld.gov.au

See site specific Participant Information Sheet and Consent Forms for site specific complaints.

Consent Form
Site: <Location>

Project Title: Australian Centre of Excellence in Melanoma Imaging & Diagnosis (ACEMID) Cohort Study

Principal Investigators: Prof H. Peter Soyer, University of Queensland

Site Principal Investigator: <Insert site principal investigator here>

- I have read the Participant Information sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.
- I understand that I will be given a signed copy of this document to keep.
- I understand that there may be downstream commercial use of some of my images and associated de-identified data for which the <University> may receive financial benefit. Under certain circumstances this benefit may be shared with University staff consistent with the appropriate University policies.
- Understand that non-identifiable data collected in this project may be used as comparative data in future projects closely related to this study.
- I may be approached again to participate in future components of this study or future studies conducted by the investigators but I am under no obligation to do so.
- I understand that participation in this study does not replace the normal care and discussions that I may have had with my treating doctors.

Participant's Name (printed) Date of Birth:

Signature: Date:

Mailing address/Email address:

Declaration by researcher*: I have given an explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's Name (printed)

Signature: Date:

Consent for Use of Images

Site: <Location>

Project Title: Australian Centre of Excellence in Melanoma Imaging & Diagnosis (ACEMID) Cohort Study

Principal Investigators: Prof H. Peter Soyer, University of Queensland

Site Principal Investigator: <Insert site principal investigator here>

Please tick below boxes if you consent to the following statements (optional):

- I consent to the inclusion of my images when publishing data from this study and in publications and presentations. I understand that images will not be identifiable.
- I consent for my skin images to be used freely in various research studies regarding skin naevi (moles), skin cancers and dermatological conditions including open access research databases. I understand that images will not be identifiable.

Participant's Name (printed) Date of Birth:

Signature: Date:

Declaration by researcher*: I have given an explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's Name (printed) (printed)

Signature: Date:

Informed Consent for Data Collection
Site: *<Location>*

Project Title: Australian Centre of Excellence in Melanoma Imaging & Diagnosis (ACEMID) Cohort Study

Principal Investigators: Prof H. Peter Soyer, University of Queensland, Brisbane

Site Principal Investigator: *<Insert site principal investigator here>*

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- I have read this document and I understand the purposes, procedures and risks of this research project as described within it.
 - I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release relevant information to *<University>* that is needed for this project. I understand that such information will remain confidential.
 - I give permission for *<State>* Cancer Registry to release pathology reports regarding my previous melanoma diagnosis (if applicable) and other types of invasive cancers (if applicable).
 - I give permission for researchers to request data collection from *<State>* Hospital Admitted Patient Data Collection.

Participant's Name (printed) Date of Birth:

Signature: Date:

Declaration by researcher*: I have given an explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's Name (printed)

Signature: Date:

Consent Form for Biological Samples

Site: <Location>

Project Title: Australian Centre of Excellence in Melanoma Imaging & Diagnosis (ACEMID) Cohort Study

Principal Investigator: Prof H. Peter Soyer, University of Queensland

Site Principal Investigator: <Insert site principal investigator here>

- I have read the Participant Information sheet and understand the purposes, procedures and risks of the research described in the project.
- I understand that I may be asked if I am willing to donate biological samples, including saliva, urine, blood and tissue, which is completely optional.

I am willing to donate biological samples for research purposes

I am willing to donate specific biological samples only. Please indicate which ones

Saliva Urine Blood Tissue

I am NOT willing to donate any biological samples

- **I understand that this study could identify a genetic defect that increases my/my family's risk for melanoma or an unrelated condition**

I would like to be recontacted via mail/email if a risk factor for a treatable condition is identified

In the unlikely event of my death before genetic findings are available, I would like to nominate _____ to receive this information

I would NOT like to be recontacted if a risk factor for a treatable condition is identified

- **In respect to the storage and use of my biological samples, I give permission for the use of my DNA and/or tissue (skin/blood) for the purpose of:**

1. This research project only Yes No

2. This research project and any future dermatological research projects Yes No

Participant's Name (printed) Date of Birth:

Signature: Date:

Declaration by researcher*: I have given an explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's Name (printed)

Signature: Date:

Withdrawal of Consent Form

Site: <Location>

Project Title: Australian Centre of Excellence in Melanoma Imaging & Diagnosis (ACEMID) Cohort Study

Principal Investigator: Prof H. Peter Soyer, University of Queensland

Site Principal Investigator: <Insert site principal investigator here>

I hereby wish to **WITHDRAW** my consent to participate in the research proposal named above effective from the date below.

Please tell us to which extent you would like to withdraw from the study. You can withdraw from participating in any further research visits, while still consent to other aspects of our research to continue. This is up to you.

Withdraw from study treatment, but agree to **RETAIN** all information collected about me to date so it can continue to be used for research.

OR

Withdraw from study treatment, but **DESTROY** all information collected about me to date so it can no longer be used for research.

I understand that:

1. no further information about me will be collected for the study from the withdrawal date;
2. information about me that has already been analysed and/or included in a publication by the study, may not be able to be destroyed; and
3. choosing to withdraw from the study will not affect my access, treatment or relationship with <insert institution>, or Health Services.

Participant's Name (printed) Date of Birth:

Signature: Date:

DO NOT SIGN