Participant Information Sheet/Consent Form

Title	**MEL-SELF: A randomised controlled trial of patient-led surveillance compared to clinician-led surveillance in people treated for localised melanoma**
Short Title	MEL-SELF
Protocol Number	X20-0106
Project Sponsor	The University of Sydney
Coordinating Principal Investigator/ Principal Investigator	Associate Professor Katy Bell
Location	Melanoma Institute of Australia (MIA) Poche Centre, the Royal Prince Alfred Hospital and Newcastle Skin Check

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project because you had surgical removal of an early stage melanoma, that was localised to the skin. The research project is testing a new way of following up people who have had a localised melanoma (in situ melanoma or stage I or II invasive melanoma). The new method uses a technology called teledermatology, which involves taking pictures of skin lesions on your body with a mobile device attached to your smartphone and uploading these images for a teledermatologist to review remotely (please note that this may not be your usual treating dermatologist).

This Participant Information Sheet tells you about the research project. It explains the tests and procedures involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Your participation is voluntary
Participation in this research is completely voluntary. If you don't wish to take part, you don't have to, and you should feel under no obligation to participate in this study. You can choose to withdraw from the study at any time. You will receive the best possible care whether or not you choose to take part.

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. The details are provided in section 12.

Storage, retention and destruction of your information
Data collected from you will be stored on REDCap, a well-accepted, secure, password-protected online platform for research data. REDCap servers are based in the University of Sydney, Australia. When we collect your information, your name will be replaced by a code.

During the study, only authorised research staff will be able to access your data. More details are provided in section 15.

If you decide you want to take part in the research project, you will be asked to sign the MEL-SELF study Consent Form. By signing it you are telling us that you:

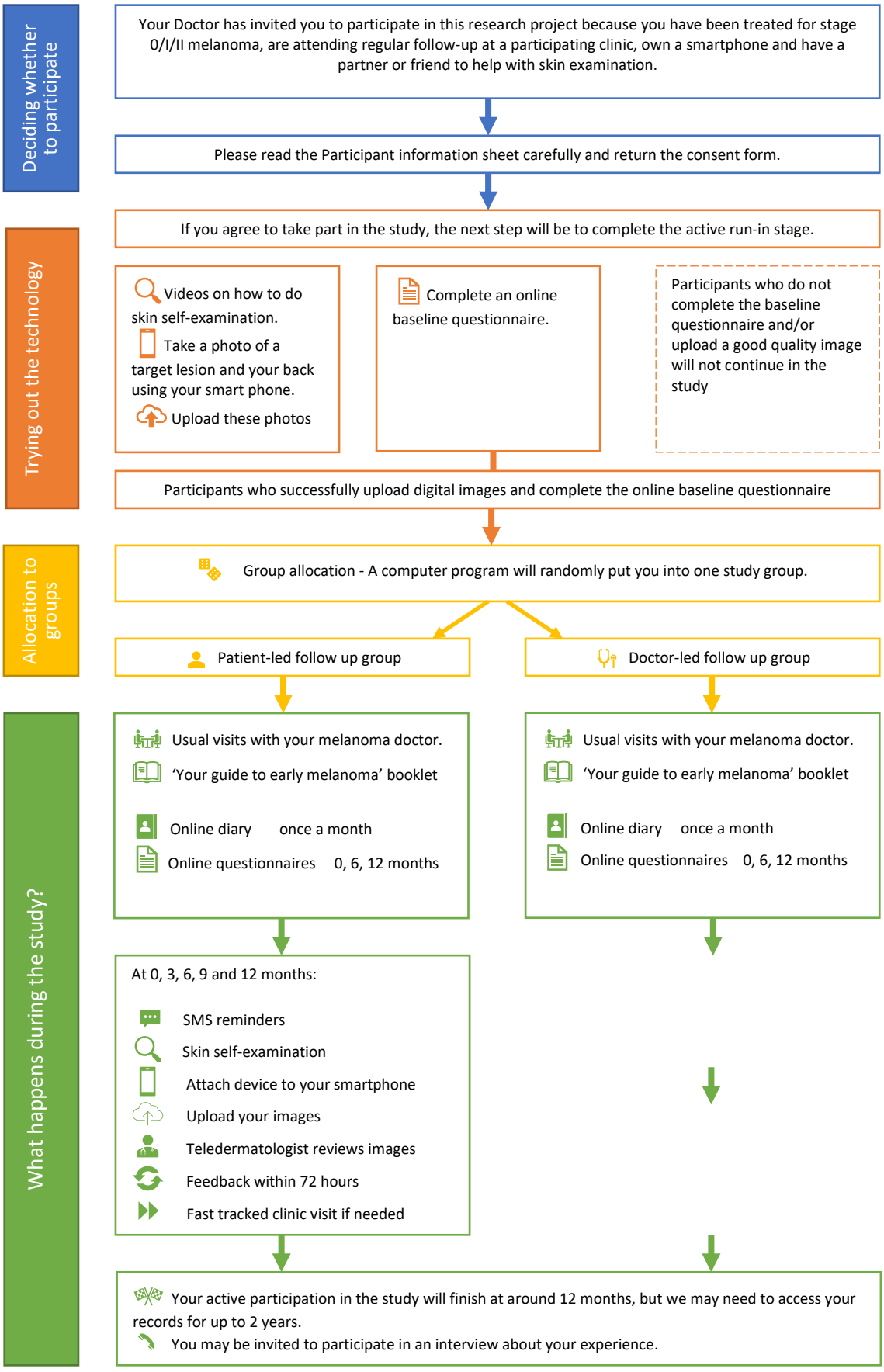
- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and procedures that are described
- Consent to the use of your personal and health information as described.

If you agree to the release of your Medicare Benefits Schedule (MBS) information to the MEL-SELF study, you will be asked to sign an additional MBS consent form. Medicare collects information on your doctor visits and the associated costs.

You will be given a copy of this Participant Information and both Consent Forms to keep.

We note that two members of the research team who perform teledermatology have a financial interest in dermatoscope companies. No other members of the research team, including all members of the core operational team based at the University, will receive any personal financial benefit from your involvement in this research project (other than their ordinary wages). The dermatoscope company does not have any financial or commercial interests in this study.

Participant schedule



2 What is the purpose of this research?

Many melanomas are found by patients or their family members between doctor's visits. Even more might be detected if patients and their partners are trained in the best way to do total body skin self-examination and have fast access to a dermatologist's opinion on anything found. This study will investigate the potential for this type of follow-up to add to early detection of melanoma through the usual regular clinic visits with the patient's doctor.

We are studying whether teledermatology (using a device attached to your smartphone to take close up photographs of your skin, sending them to a dermatologist through an app, and receiving the dermatologist report through the app), may lead to earlier diagnosis of melanomas and other skin cancers. We are also studying whether changing follow up care has an impact on your thoughts and feelings about melanoma.

We will use 2 different medical devices in this study: MoleScope Lite and MoleScope II. Both devices take pictures of skin lesions and are used with smartphone apps which store and transmit these images. Both devices have been approved for use by the Australian Government.

This research has been initiated by the study doctor, Associate Professor Katy Bell and has been designed in conjunction with doctors who treat melanoma and non-melanoma skin cancers. This study is sponsored by The University of Sydney. The funding for the study comes from the National Health and Medical Research Council of Australia.

3 What does participation in this research involve?

You will be asked to read and electronically sign the consent form to confirm that you understand what is involved in this study and that you agree to take part. Before signing the eConsent, you are welcome to contact the research team to discuss anything that is not clear to you or any questions you may have.

If you are eligible to participate in this study and you agree to participate, you will enter the "active run-in" phase of the study. At this stage you should choose a partner who can assist with taking pictures with the smartphone. In this phase you (and your partner) will:

- view web-based videos on how to do total body skin self-examination.
- use your smartphone to take an image of the "target" lesion (identified by your doctor as the one of most interest at your last clinic visit) and an image of your back.
- practise uploading the digital photos of the target lesion and your back to the study's online platform.
- complete a baseline online questionnaire.

If you successfully complete the active run-in phase, then you will continue into the main study. You will then be enrolled in the study for a duration of 12 months.

You will be participating in a randomised controlled research project. We do not know the best method of follow-up after the initial treatment of melanoma. To find out we need to compare different models. A computer program will randomly put participants into one of two groups with different models of follow-up care which are outlined in Section 4. The results will be compared to see if one is better than the other. If you decide to take part in this study, neither you nor your doctors can decide which group you will be in. There is an equal chance you will be in either group.

This research study has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoid study doctors or study participants jumping to conclusions that are not based on the evidence.

You will not be paid for participating in this research project. In fact, there are possible additional costs from your participation, as your usual method of payment (including out of pocket costs) will apply for all your appointments, investigations and treatments whether or not these result from your findings on total skin self-examination and teledermatology review.

The researchers request permission to access your medical records and to contact your GP and other doctors who you see regarding your melanoma to obtain information relevant to this study. In addition, we ask permission to collect data about melanoma diagnoses recorded in the NSW Cancer Registry, and the MBS claims database. Data will be collected from these sources while you are participating in the study and for up to one year after you finish. Please read section 15 for more information about the types of data we will collect about you and how the data will be managed.

4 What do I have to do?

If you decide to take part in this study, you will be randomly put into one of two groups.

- The doctor-led follow up group will continue to have their usual clinic visits, investigations and treatment as recommended by their doctor.
- The patient-led follow up group will submit images for teledermatology review every 3 months **in addition** to their usual clinic visits, investigations and treatment as recommended by their doctor.

Whichever group you are in you will:

- Continue your usual follow-up clinic appointments and treatment as recommended by your melanoma doctor. Copies of the pathology reports for any skin biopsies or excisions you have while you are participating in the trial will be collected by the study team.
- Receive an educational booklet ‘Your guide to early melanoma’.
- Complete 3 online questionnaires: one at the beginning of the study (during “active run-in” phase), one at 6 months and one at 12 months. These questionnaires will ask about your experiences with melanoma, including the number of visits you have had to any doctor regarding your melanoma since the study began, your experience with total body skin self-examination and your thoughts and feelings about melanoma.
- Complete a monthly online patient diary which will record your clinic and travel costs.
- You will also be able to participate in telephone interviews at 12 months to give feedback on your experiences, if you wish.

If you are in the patient-led follow up group, you will also:

- Receive a mobile dermatoscope (a device that allows close-up images of skin lesions to be taken) to attach to your smartphone. This works with a smartphone app.
- Receive training from study staff for you and your partner in using the dermatoscope and app, delivered one-on-one by web conferencing.
- Receive written and video instructions on how to use the dermatoscope and the associated smartphone app.
- Receive ongoing access to the web-based videos on how to do total body skin self-examination.
- Submit 5 sets of images: on receipt of your mobile dermatoscope and instructions, and

then at 3 months, 6 months, 9 months, and 12 months. You will use your dermatoscope to take pictures of skin lesions. You will submit an image of a 'target' skin lesion (identified by your doctor as the one they are most interested in), and up to 8 additional lesions that you identify through total body skin self-examination that you are concerned about.
- Receive email and SMS text reminders every 3 months to perform total body skin self-examination and submit images of the target skin lesion and other skin lesions.
- Receive teledermatologist review of the images you submit. The teledermatologist who reviews your images may not be your usual dermatologist. A report will be sent to you within 3 working days. You will receive advice on whether you need to attend an additional unscheduled clinic visit, or whether you can safely wait for your next routine appointment with your doctor. A MEL-SELF staff member will contact you if a delay beyond 3 working days is expected for any reason.
- Receive fast tracked unscheduled visits for review of lesions if needed.
- You will also be able to participate in telephone interviews at the beginning of the trial, at 6 months and 12 months to give feedback on the intervention, if you wish.

5 Other relevant information about the research project

This research project will include 600 people who have been treated for localised melanoma. The skin cancer clinics involved include the Melanoma Institute of Australia (MIA) Poche Centre, the Royal Prince Alfred Hospital and Newcastle Skin Check. The research team includes experts in melanoma diagnosis and treatment, experts in psychology, experts in health economics and researchers from the University of Sydney, as well as doctors who treat people with melanoma (Dermatologists, Surgeons and GPs). This study will expand on a pilot study of 100 participants which has now finished.

6 Do I have to take part in this research project?

Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the staff who are caring for you.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this clinic. You will receive the current recommended follow-up care for localised melanoma if you do not participate in the study.

8 What are the possible benefits of taking part?

We cannot guarantee that you will receive any benefits from this research; however, possible benefits may include improved follow-up care for patients who have been treated for localised melanoma. This may include earlier detection of new or recurrent melanoma and non-melanoma skin cancer. It may also improve patient confidence and well-being. These benefits may apply to participants in the trial as well as other people in the future.

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

Medical procedures often cause side effects. One possible side-effect of total body skin self-examination and teledermatology is anxiety related to thoughts about melanoma recurrence. Anxiety could be mild, moderate or severe. If you think that this might affect you or you have any questions, please talk with your doctor. Your doctor will also be looking out for signs of anxiety.

Many side effects go away shortly after a procedure ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your doctor may need to stop your use of the trial medical device and procedures. Your doctor will discuss the best way of managing any side effects with you.

There may be side effects that the researchers do not expect or do not know about and may be serious. Tell your doctor immediately about any new or unusual symptoms that you get.

If you become upset or distressed as a result of your participation in the research, your doctor will be able to arrange for counselling or other appropriate support using services that are currently available at the treatment centre. Any counselling or support will be provided by qualified staff who are not members of the research project team.

If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

10 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the medical device and procedures that are being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

11 Can I have other treatments during this research project?

This research project should not impact your treatment for other medical conditions.

12 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing. If you want to withdraw only from the part of the study relating to the MBS, you can withdraw from this part of the study at any time by completing and signing the ‘Participant Withdrawal of Consent Form (MBS)’.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you. For the MBS component, you will be able to choose whether the study will destroy or retain the information it has collected about you by choosing one of these options on the ‘Participant Withdrawal of Consent Form (MBS)’. Where both boxes are ticked in error or neither box is ticked, we will retain the MBS information collected about you.

You should be aware that data collected by the sponsor up to the time you withdraw, as well as data routinely collected by the treating clinic, Medicare and NSW Cancer Registry up to a maximum of 2 years from the time of randomisation, will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

Please note that while you can withdraw from this study at any time without giving a reason, your continued contribution would be much appreciated. Every participant's contribution will greatly assist us in producing accurate and meaningful results.

If you withdraw from the study, we will ask you whether you would like to participate in an interview about your experience participating in the MEL-SELF Trial. The interviews will be conducted by phone. If you don't wish to take part, you don't have to, and you should feel under no obligation to participate in the interview.

13 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The intervention being shown not to be effective
- The intervention being shown to work and no need further testing.

14 What happens when the research project ends?

You will need to return the mobile dermatoscope to the study team and will not have access to teledermatology when the project ends. You can return the dermatoscope in a reply-paid envelope that we will send you. The research team will analyse and interpret the results from the project to assess the potential benefits and harms of the intervention.

You will have the opportunity to opt-in to access results of this research project via a written summary of its findings at the conclusion of the study.

Part 2 How is the research project being conducted?

15 What will happen to information about me?

By signing the eConsent form, you consent to the study doctor and relevant research staff collecting and using personal information about you, including contact details, for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. All electronic information collected throughout the study will be stored securely in a password protected database managed by the researchers at the University of Sydney. Hard copy materials will be protected during and after the project as they will be stored in a locked filing cabinet in a secure room at the University of Sydney.

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Non-identifiable electronic data and hard copies will be stored for a period of 15 years. After this, electronic data will be destroyed by removing and deleting all files from the University secure server and hard copies will be destroyed using University shredding facilities. The linked data including data from MBS and NSW Cancer Registry we will collect as part of this study will not be used in any future or unspecified research outside of this study.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

In accordance with relevant Australian and NSW privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Your images

You will be asked to provide consent for the collection of your images during the research project and for future use by our research group. Future use may involve a comparison of the performance of the two dermatoscope devices, and comparison of teledermatology reports across different dermatologists.

You will upload images to the MoleScope App for secure transmission to a web-based platform where dermatologists and research staff can view them. The platform is based in Australia and meets privacy requirements under Australian law.

Copies of your images obtained for the purpose of this research project will be transferred to The University of Sydney. After the study finishes, images will be stored in non-identifiable form for a period of 15 years. After this, they will be destroyed by removing and deleting all files from the University secure server. Your images will not be sold by The University of Sydney.

Your health information

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. The researchers request permission to access your melanoma clinic medical records and to contact your GP and other doctors who you see regarding your melanoma to obtain information relevant to this study. By signing the eConsent form, you agree to the study team accessing health records if they are relevant to your participation in this research project. Information about your participation in this research project may be recorded in your health records.

In addition, we ask permission to collect data about your melanoma diagnoses (e.g. date of diagnosis, age at diagnosis, cancer type, stages of melanoma, number of primary sites) from the NSW Cancer Registry and data about your Medicare financial claims for any skin cancer procedures recorded in the MBS data.
Any health information used from these data sources will be in a form that will not identify you. This means that your name, date of birth and address will be removed to ensure your privacy is protected. Your health information will be managed completely confidentially and used only for the purpose of the research as described for this study. This information will be collected while you are participating in the study and for up to one year after you finish.

With your permission, your health information will be collected from the NSW Cancer Registry and Services Australia. There is a small risk to your privacy because personal information is used in the record linkage process for the linking of your health information. This risk will be minimised by separating the processes of record linkage and data analysis. The record linkage only uses personal information such as name, date of birth, and home address. At the time of linkage, a unique personal identification number will replace your personal information and therefore cannot be connected back with other records for you or any other participant.

The linked health information on your melanoma diagnoses as provided by the NSW Cancer Registry and MBS data as provided by Services Australia will not be shared beyond the research team. If you want to opt-out of the linking of your health information to the NSW Cancer Registry, there is an option to indicate this choice on the consent form by ticking the box for opt-out. For the MBS component, you will be asked to sign a separate consent form authorising MEL-SELF study to access your MBS data related to the claims for item numbers related to melanoma and other skin cancers as outlined in the consent form. The consent form will be sent securely to Services Australia who holds MBS data confidentially.

Your health records and any information collected and stored by the study doctor during the study may be reviewed (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Human Research Ethics Committee, the study sponsor (The University of Sydney) and by regulatory authorities, such as Australia's Therapeutic Goods Administration (TGA) or as required by law. In these circumstances, the ethics committee or TGA may access non-coded identifiable information. By signing the consent form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

16 Complaints and compensation

If you have any concern about any aspect of the study, you should ask to speak with your study doctor or research co-ordinator who will do their best to answer your questions (contact details on page 11). If you remain unhappy and wish to complain about any aspect of the way you have been approached or treated during the course of this trial, the normal hospital complaints mechanisms are available to you. We recommend that you obtain a copy of your hospital's complaints procedure or policy if you intend to make a complaint. Concerns should be raised by speaking to a member of staff at your hospital or by talking to the local Patient Advice and Liaison Service, which has been established in every hospital. If you have any complaints about any aspect of the project, the way it is being conducted you may contact the Human Research Ethics Committee (HREC) of the Royal Prince Alfred Hospital (contact details are provided on page 11).

If you suffer any injuries or complications as a result of this study, you should contact the study team as soon as possible, who will assist you in arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. You do not give up any legal rights to compensation by participating in this study.

17 Who is organising and funding the research?

The University of Sydney has received payment from the Australian National Health and Medical Research Council (NHMRC) to undertake this research project. Neither the University of Sydney nor the NHMRC is expecting any direct financial benefits from this research.

You will not benefit financially from your involvement in this research project.

Two members of the research team who will be performing teledermatology have a financial interest in MoleScope products. No other members of the research team, including all members of the core operational team based at the University, will receive any personal financial benefit from your involvement in this research project.

19 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 the Royal Prince Alfred Hospital.

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.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor (Royal Prince Alfred Hospital: Associate Professor Robyn Saw (Ph: 02 9911 7210)/ Melanoma Institute Australia (Poche Centre): Dr Linda Martin (Ph: 02 9911 7277)/ Newcastle Skin Check: Dr Anthony Azzi (Ph: 02 40328700) or any of the following people:

Clinical contact person

Name	Katy Bell
Position	Co-ordinating Principal Investigator
Telephone	0415764321
Email	katy.bell@sydney.edu.au

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

Newcastle Skin Check

Name:	Monjura Nisha
Email:	monjura.nisha@sydney.edu.au

Melanoma Dermatology Trust

Name:	Dorothy Drabarek
Email:	dorothy.drabarek@sydney.edu.au

Sydney Melanoma Diagnostic Centre

Name:	Jake Williams
Email:	jake.williams@sydney.edu.au

Sydney Melanoma and Surgical Oncology

Name:	Ellie Medcalf
Email:	ellie.medcalf@sydney.edu.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 name	Sydney Local Health District (RPA Zone)
Contact	HREC Executive Officer
Telephone	02 9515 6766
Email	SLHD-RPAEthics@health.nsw.gov.au
Protocol	X20-0106

Reviewing HREC approving this research and HREC Executive Officer details

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 or SLHD-RPAEthics@health.nsw.gov.au and quote protocol number X20-0106 & HREC/2019/ETH13612.

The conduct of this study at the Royal Prince Alfred Hospital has been authorised by the Research Governance Officer. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on 02 9515 7899 and quote protocol number X20-0106 & HREC/2019/ETH13612.

If you have a privacy complaint in relation to the use of your MBS data you should contact the Office of the Australian Information Commissioner. You will be able to lodge a complaint with them.

Website: www.oaic.gov.au
Telephone: 1300 363 992
Email: enquiries@oaic.gov.au
Mail: GPO Box 5218, Sydney NSW 2001