|  |  |
| --- | --- |
|  |  |

**PARTICIPATION INFORMATION SHEET**

|  |  |
| --- | --- |
| **Title** | A pilot randomised controlled trial of patient-led surveillance compared to clinician-led surveillance in people treated for localised melanoma  *[Project Title]* |
| **Short Title** | *ANZMTG 02.17 MEL-SELF* |
| **Protocol Number** | *[Protocol Number]* |
| **Principle Investigator**  **Coordinating Principal Investigator** | *Dr Katy Bell*  *[Coordinating Principal Investigator/Principal Investigator]* |
| **Location** *(where CPI/PI will recruit)* | *[Institution where PI will recruit]* |

**1 Introduction**

You are invited to take part in this research project. This is because you have an early stage melanoma. The research project is testing a new treatment options for melanoma stage 0/I/II. The new treatment is called teledermatology which is the use of electronic communication to transfer medical information for a dermatologist to review remotely.

This Participant Information Sheet Form tells you about the research project. It explains the tests and treatments 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 to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the 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 treatments that are described

• Consent to the use of your personal and health information as described.

**2 What is the purpose of this research?**

Most melanomas are detected by patients or their family members between scheduled visits; even more might be detected if patients are trained in total body skin self-examination (SSE). The objective of this study is to investigate whether a Smartphone App with videos showing how to perform skin self-examination and teledermoscopy (taking close up photographs of your skin using your phone) may lead to performing skin self-examination more regularly and increases confidence in doing this compared to standard education to learn about skin self-examination from a booklet alone (usual care).

**3 Why am I being invited to participate?**

You have been invited to participate in this research study because you are 18 years or over and have been treated for a first primary melanoma stage 0/I/II and are undergoing regular melanoma follow-up in clinic.

**4 What does participation in this research involve?**

Before any trial assessments can be performed, you will be asked to read and sign the consent form and participation card (attached to this information sheet) to confirm that you understand what is involved in this study and that you agree to take part in the trial. These forms will need to be returned to the Research Team during your clinic visit or using the reply-paid envelope provided.

If you meet the eligibility requirements to participate in this study and agree to participate, you will be enrolled in the study for the duration of 6 months.

Once the research team have received your consent form, you will be randomly assigned to one of two treatment groups (intervention and control) so that the researchers can compare the two models of melanoma surveillance. There is a 50% chance to be assigned to the ‘intervention’ group and a 50% chance to be assigned to the ‘control’ group.

Participants in both groups will receive an educational booklet ‘Your guide to early melanoma’. Participants in both groups will also be asked to complete a two monthly patient diary and 2 questionnaires over a 6 month period. The first one after your initial follow up appointment and the second at 6 months after your follow-up appointment. The purpose of these questionnaires is to learn more about your experiences with melanoma, including the number of visits you have had to any doctor regarding your melanoma since the study began, experience with Skin Self-Examination and your thoughts and feelings about melanoma. The patient diary will capture your clinic and travel costs.

If you are in the ‘intervention’ group you will also receive:

* A dermatoscope (this device allows you to take magnified images of skin lesions under polarized light for electronic transmission to a specialist) to attach to a smartphone and work in conjunction with a Smartphone App. A dermatologists will review the reports and images you submit in the app within 3 working days (if not the study coordinator will notify you with information on the delay). The dermatologist will then provide you with a clinical recommendation after they review your images.
* Written and video instructions on how to use the dermatoscope and the associated Smartphone App.
* Email and SMS text reminders every 2 months to perform self-examination on the Smartphone App and to complete a survey. The skin checker survey will also provide you with instructional videos on guided total skin self-examination and electronic reporting.

If you are in the ‘control’ group you will not have to perform self-examinations every two months.

In both groups of the study you will continue your routine follow-up appointments depending on your level of skin cancer risk. You will receive treatment for suspicious lesions as per the current Australian Guidelines. You may be asked to undertake investigation of a suspicious lesion (e.g. skin biopsy) because it is a routine part of treatment and information about the skin biopsy will also be collected by the study team.

In addition, the researchers would like your permission to access to your medical record and to contact your GP and other doctors that you see regarding your melanoma to obtain information relevant to this study.

**5 What types of medical information will be accessed?**

The research team will collect the following medical information from your melanoma clinic database during the study period:

* Your melanoma stage
* The number of lesions surgically evaluated
* Clinical characteristics and/or pathology reports from biopsies of melanoma, non-melanoma skin cancers and benign lesions evaluated, including from where on your body they were located/removed.
* Clinical images

**6 Are there any costs associated with this study?**

There are no additional costs associated with participating in this research project, nor will you be paid. You will have to pay for your regular scheduled appointments and treatments.

**7 Are there any risks associated with this study?**

We do not anticipate that there would be any risks associated with participation.

**8 Who is organising and funding the research?**

This is an investigator-initiated clinical trial. This means that the concept of this study has been designed by the doctors who treat melanoma and non-melanoma skin cancers. This study is being sponsored by The University of Sydney. The scientific quality of the protocol is also endorsed by the Australia and New Zealand Melanoma Trials Group (ANZMTG), which will be overseeing the coordination of the study. The funding for the study comes from the National Health and Medical Research Council (NHMRC).

**9 Do I have a choice?**

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.

**10 What will happen to my information?**

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to your participation in this study.

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 ANZMTG) 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 as mentioned above.

It is anticipated that the results of the study 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, except with your express permission.

Any personal details you provide, such as your name, email address and telephone number, will be stored in a password protected electronic database and will only be used to contact you in relation to this study. Your questionnaires will be assigned a unique study number and will only be accessed and recorded using that number. If you prefer to complete the questionnaires using the internet (online), web-based questionnaires will be administered using a secure website and only the researchers will have access to the information you provide. All web-based surveys will be password protected and all participants will have a unique password. All information gathered throughout the study will be kept in a password protected database managed by the researchers at the University of Sydney. The study results may be presented at conferences or in scientific publications, but individual participants will not be identifiable in any such presentations.

**11 What if there is a problem?**

If you have any concern about any aspect of the study, you should ask to speak with your study doctor or research nurse who will do their best to answer your questions (contact details at the end of this document). 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 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.

**12 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). This study has been reviewed and given approval by the Royal Prince Alfred Hospital Ethics Committee.

[If appropriate:] The conduct of this study at [Name of Institution] has been authorised by the [Name of Local Health District]. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer [or other officer] on [telephone number] and quote protocol number [insert local protocol number].

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007, updated March 2018). This statement has been developed to protect the interests of people who agree to participate in human research studies. It can be accessed at [www.nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research](http://www.nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research)

**13 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 on [phone number] or any of the following people:

**Clinical contact person**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

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

**Complaints contact person**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

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 | Royal Prince Alfred Hospital Ethics Commitee |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

**Reviewing HREC Complaints Officer:**

**Local HREC Office contact (Single Site - Research Governance Officer)**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

**PARTICIPATION CONSENT FORM**

|  |  |
| --- | --- |
| **Title** | A pilot randomised controlled trial of patient-led surveillance compared to clinician-led surveillance in people treated for localised melanoma  *[Project Title]* |
| **Short Title** | *ANZMTG 02.17 MEL-SELF* |
| **Protocol Number** | *[Protocol Number]* |
| **Principle Investigator**  **Coordinating Principal Investigator** | *Dr Katy Bell*  *[Coordinating Principal Investigator/Principal Investigator]* |
| **Location** *(where CPI/PI will recruit)* | *[Institution where PI will recruit]* |

I, ......................................................................................................................................

*[full name]*

of ............................................................................................................…….

*[address]*

have read and understood the Information for Participants on the above named research study

and have discussed the study with

..............................................................................................

[Doctor and/or Member of the Research team name]

I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

I understand that if I am allocated to the ‘intervention’ group, any photos of my skin taken with the App will be seen by my doctor and the research team, and I agree to this.

I understand that my participation in this study will allow the researchers and others, as described in the Information for Participants, to have access to my medical record and, if required, to contact my GP and other doctors that I see regarding melanoma to obtain information relevant to this study, and I agree to this.

I freely choose to participate in this study and understand that I can withdraw at any time.

I also understand that the research study is strictly confidential.

I hereby agree to participate in this research study.

**NAME:**

**...........................................................................................................**

**SIGNATURE:**

**...........................................................................................................**

**DATE:**

**...........................................................................................................**

**NAME OF WITNESS:**

**..................................................................................................**

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**SIGNATURE OF WITNESS:**

**..................................................................................................**