

 **Participant Information Sheet/Consent Form**

**Non-Interventional Study** -*Adult providing own consent*

Alfred Health

|  |  |
| --- | --- |
| **Title** | TRialHub tELetriAge pilot studY |
| **Short Title** | RELAY |
| **Project Number** | 88766 |
| **Project Sponsor** | Alfred Health  |
| **Coordinating Principal Investigator** | Assoc Prof Victoria Mar |
| **Associate Investigator(s)** | Dr Ken Ip, Dr Maithili Sashindranath, Assoc Prof Chris McCormack, Dr Michelle Goh, Dr Ryan Toholka, Dr Dennis O’Connor, Ms Amy Clark, Ms Narelle McPhee, Mr Ayooluwatomiwa Oloruntoba, Prof Monika Janda, Prof Rory Wolfe |
| **Site Principal Investigator** | [insert site PI] |
| **Location**  | [insert site] |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project, TRialHub tELetriAge pilot studY (RELAY). This is because you have visited your General Practitioner for a skin check which identified one or more skin lesions requiring further attention. The research project aims to take advantage of technology to deliver more streamlined diagnosis and management of skin cancers.

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

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or 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 section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to research that is described

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

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

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

Many regional areas do not have adequate access to dermatology services and waiting times can be long. Referrals from General Practice to specialist skin cancer services do not typically include high quality images of lesions of concern, making it difficult to effectively triage (prioritise) urgent cases or provide reassurance to those less urgent. This study will determine the feasibility of a remote (tele)triage service to improve diagnosis and management pathways for people with skin cancer.

Melanoma is the third most common cancer in both men and women in Australia, and an important cause of cancer-related deaths. Treatment of melanoma and other skin cancers in regional and rural Australia can be delayed due to limited availability of and difficulty accessing GPs with special interest in skin cancers, dermatologists and surgeons. Importantly, early detection of skin cancer reduces the risk of severe disability and death because they are detected when less invasive, and so have a lower probability of spreading to other parts of the body.

Teledermatology is the process whereby a dermatologist receives digital images of patients’ skin lesions and interprets these images remotely to make diagnoses and treatment recommendations. This is enabled by advances in imaging technology and secure image sharing platforms.

Recent studies have suggested that computer algorithms can analyse images of skin cancer with the same accuracy as trained dermatologists, but few studies have tested computer algorithms in the clinical setting to determine whether they can improve management of skin lesions. Development of a computer-assisted teledermatology service in regional and rural centres has the potential to improve access to dermatologists, multidisciplinary teams and clinical trials, thereby avoiding delays to diagnosis and management of melanoma and skin cancers.

The overall goal is to assess the feasibility of a teledermatology service in [insert location], its impacts on patient care pathways, and its acceptability to patients and GPs and dermatologists, while secondarily testing the utility of a computer algorithm as an upskilling tool. Central to this is the role of the regional care navigator to assist patients through their care pathway.

This research has been initiated by the study doctor, Assoc Prof Victoria Mar and funded by the TrialHub, a Federal Government initiative to build capacity and improve access to clinical trials in regional areas. The results of this research will be used by Monash University student Ayooluwatomiwa Oloruntoba to obtain a Doctor of Philosophy degree.

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

To improve timely access to skin cancer diagnosis and management, your General Practitioner (GP) will take two photos of any lesion(s) of concern:

* **Clinical photo**: Taken with a standard camera from afar and up-close.
* **Dermoscopic photo**: Taken using a specialised magnifier with lighting that is placed against the skin.

Your GP will ask your permission to send a referral, including images of your skin lesion(s), together with information about your risk factors, the history of the skin lesion(s) of concern, and your contact details to the Regional Care Navigator (a nurse) at “Insert Site” via the secure TeleTriage platform, DermEngine™. If you provide verbal consent, your GP will provide you with a copy of the Patient Information and Consent Form and send the referral to the Regional Care Navigator who will contact you.

The Regional Care Navigator will first assess the quality of the photos referred by your doctor. If images are of reasonable quality, the Regional Care Navigator will send the referral and images immediately to a dermatologist at [insert referral location] for remote assessment. If re-imaging is required due to poor quality or insufficient images, the Regional Care Navigator will contact you to arrange a face-to-face appointment at “Insert Site” during which high resolution photos of the affected skin areas will be taken. This appointment, if required, will last approximately 30 minutes.

The Regional Care Navigator will contact you for your consent to use information contained within your referral (risk factors, lesion history, age, gender, provisional diagnosis) and images for the purpose of this research study and request a signed copy of the Patient Information and Consent Form. If you do not wish to consent to the study, your images will still be reviewed via the teledermatology service to avoid any delays in management, and you will receive standard care, but your data (including images) will not be further analysed by computer algorithms or entered into the study database.

The dermatologist will generate an electronic report with their diagnostic opinion and management recommendation. This report will be sent to your GP and the Regional Care Navigator. The Regional Care Navigator will contact you with a management plan. If the dermatologist recommends management of your skin lesion by your GP, your GP will arrange a follow-up with you directly. Any referrals to specialist clinics within “Insert Site” or to private Specialists will be coordinated by the Regional Care Navigator. If a lesion is biopsied or removed during the course of your care, a copy of the pathology report will be requested by the Regional Care Navigator.

As part of the study, we will be investigating whether a computer based decision support tool might be useful to upskill the Regional Care Navigator and improve their triage decisions. The computer’s decision support tool will not be used by the dermatologist and GP so that it does not influence their decisions. The Regional Care Navigator will record their computer-assisted triage plan and, as a safety precaution, in cases where the dermatologist’s assessment differs significantly from the computer’s assessment, the Regional Care Navigator will ask for a second review from the dermatologist.

After receiving advice regarding your skin lesion, you will be asked to complete a survey to evaluate your experience using this new service, which should take less than 10 minutes of your time. This survey will be sent to you via email from the RELAY REDCap database.

You may also be invited to participate in the Australian Centre of Excellence for Melanoma Imaging and Diagnosis (ACEMID) cohort study (optional), which enables use of a VECTRA skin imaging machine at “Insert Site” for 3D Total Body Photography. This will involve a separate consent form. If you consent to participate in the ACEMID cohort study, any additional lesions of concern that are identified will also be recorded in the RELAY REDCap study database.

There are no costs associated with participating in this research project, nor will you be paid.

**4 What do I have to do?**

This study is open to all adult patients attending participating GP clinics within the “Insert Site” catchment area, who require skin cancer assessment.

You are eligible to be included in the study if you meet ALL of the following criteria:

1. You have at least 1 lesion that is of concern to you or your doctor.

2. You are willing to undergo clinical photography for skin lesion(s) of concern.

3. You are aged 18 years or older.

4. You are able to understand information written in English and have the capacity to provide informed consent.

5. You hold a valid Medicare card

6. Have no significant visual impairment

You will not be restricted from entering or continuing participation in other trials or projects.

**5 Other relevant information about the research project**

This pilot study aims to recruit approximately 100 participants to assess feasibility of teletriage. If the pilot is feasible and the teletriage platform is acceptable to patients, GPs and dermatologists, it will be trialled in a larger study in additional regional areas.

This study is a collaboration between clinicians and researchers at Alfred Health, Peter MacCallum Cancer Centre, [Insert Site], Bendigo Primary Care Centre and Monash University.

**6 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 do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with [Insert Site].

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include requesting a routine referral from your GP to the most appropriate service at [Insert Site] without use of your data for research. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

**8 What are the possible benefits of taking part?**

We cannot guarantee that you will directly benefit from this research project. Taking part may benefit you by providing rapid access to a dermatologist assessment of skin lesions you or your GP are concerned about and facilitate more timely management. Additionally, you may be offered the opportunity to participate in other clinical trials should you be eligible.

If the accuracy of the computer algorithm is on par with that of the dermatologist’s remote assessment, computer assisted triage may provide more streamlined and efficient access to high quality care for people living in rural and regional communities.

The new service implemented in this study may or may not lead to improvements in care pathways for patients in the future. However, this study aims to further medical knowledge and this may improve management of patients with melanoma and other skin cancers in the future.

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

If the photos taken by the GP are not of sufficient quality to make an assessment, you will be invited to an appointment at [Insert Site] for repeat photos to be taken.

Remote assessment of a photograph by a dermatologist can be more challenging than a face-to-face assessment. If you continue to be concerned about a lesion or develop any changes you should return to your GP for review.

**Biopsy and/or skin cancer removal**

If the teledermatologist recommends that a lesion should be biopsied or removed by your doctor or a specialist, and you agree to that taking place, the procedure for the biopsy/removal is no different in the study to that performed in routine clinical practice and would occur either in the GP clinic or in a specialist clinic (surgeon or dermatologist). Participation in this study does not alter the risks associated with routine skin biopsy/removal procedures.

A skin biopsy or removal may cause pain or bruising at the procedure site, a possible reaction to anaesthesia or numbing agents, irritation from stitches or staples, and the possibility of infection. The nature and type of biopsy or removal will be explained in detail to you by your treating doctor and all the care will be taken to avoid risk of side effects from the procedure. Biopsies and removal of skin cancers are standard of care.

**10 What will happen to my test samples?**

Blood and tissue will not be collected during the research project. Any skin biopsies taken will be for routine clinical care. The skin biopsy results from pathology will be recorded in the RELAY REDCap database.

**11 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is 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.

**12 Can I have other treatments during this research project?**

You will not be restricted from any treatments, entering or continuing your participation in other trials or projects.

**13 What if I withdraw from this research project?**

If you decide to withdraw from this research project, please notify a member of the research team when you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

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, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you withdraw from the research project.

If further photography is required or a biopsy is recommended, withdrawal of consent prior to these being taken will exclude them from input into the database as part of the research project.

**14 Could this research project be stopped unexpectedly?**

It is unlikely that the research will be stopped unexpectedly.

**15 What happens when the research project ends?**

When the project ends, the Teletriage service will no longer be available and you will be able to continue to visit your GP for any concerns about your skin. All data collected will be analysed at the end of the project and results may be published in a medical journal. Results will also be included in the thesis for Mr Ayooluwatomiwa Oloruntoba’s PhD degree. Results will be published and will be made available to interested participants as printed research summary reports at the GP practice.

**Part 2 How is the research project being conducted?**

**16 What will happen to information about me?**

The consent form will be emailed via the RELAY REDCap database survey function; it can be signed electronically or scanned and returned as an attachment by email.

By signing the consent form, you consent to the study doctor and relevant research staff collecting and using personal information about you for the study. Any information obtained in connection with this research project that can identify you will remain confidential. Your personal 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.

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.

You may also provide optional consent for the use of your non-identifiable images, such as photographs of your skin lesion and/or biopsy specimen, for future research projects related either to this study or the same general area of research.

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 Alfred Hospital Ethics Committee, or as required by law. In these circumstances, the ethics committee may access non-coded identifiable information. By signing the consent form, you authorise release of or access to this confidential information as noted above.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information. Any information obtained for the purpose of this research project and for the future research described in Section 16 that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

Information about your participation in this study will be recorded in your health records. Electronic study data collected through the RELAY REDCap database will be directly stored on infrastructure located in Australia. All data and study-related documentation will be maintained for at least 15 years following completion of the study.

**What will happen to images taken of my skin?**

The photographs of your skin lesion(s) will be shared by your GP with the Regional Care Navigator and dermatologist via the DermEngine™ platform developed by MetaOptima Technology Inc. This is a program that facilitates imaging, documentation and remote assessment of skin lesions.

Clinical information alongside photographs of skin lesions will be submitted for dermatology review, during which the data is stored securely on Amazon Web Services cloud computing platform (Australia) in to ensure data protection and security in adherence with current guidelines. A computer algorithm incorporated into the Dermengine software has been developed as an educational tool, whereby the photographed lesion is analysed using deep learning techniques and compared against a visual search through a database of thousands of pathology-labelled images. This tool will be accessed by the Regional Care Navigator.

Other genuine researchers may request access to re-identifiable data in the future. Access will only be granted if they agree to preserve the confidentiality of the information as requested in this form. Their access will also require approval from the original research team as well as approval from a Human Research Ethics Committee at their home institution. If you agree to provide your consent for the use of your non-identifiable images in further research, you can tick the relevant box on the consent form. You are not obliged to give your consent for this. If you do not give permission for the use of your images in further research this will not affect your participation in this research project, your treatment or your relationship with your treating (or study) doctors.

Only the Regional Care Navigator will be able to connect your study ID with your personal details. 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, including images, will be provided in such a way that you cannot be identified, except with your express permission.

**17 What if I get injured in the research?**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. As 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.

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

This research project is being conducted by Assoc Prof Victoria Mar, Alfred Health. It is being funded by Trialhub, a Federal Government initiative to improve Clinical Trials capabilities in regional areas.

You will not benefit financially from your involvement in this research project even if, for example, your data (or knowledge acquired from analysis of your data) prove to be of commercial value to Alfred Health.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. As 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.

**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 Alfred Hospital Ethics Committee and the Monash University HREC.

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 on 03 9076 2000 or the Regional Care Navigator on 03 5454 7210.

 **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 | Alfred Health  |
| HREC Executive Officer | N/A |
| Telephone | (03) 9076 3619 |
| Email | research@alfred.org.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

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

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

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | TRialHub tELetriAge pilot studY |
| **Short Title** | RELAY |
| **Project Number** | 88766 |
| **Project Sponsor** | Alfred Health |
| **Coordinating Principal Investigator** | Assoc Prof Victoria Mar |
| **Site Principal Investigator** | [insert site PI] |
| **Associate Investigator(s)** | Dr Ken Ip, Dr Maithili Sashindranath, Assoc Prof Chris McCormack, Dr Michelle Goh, Dr Ryan Toholka, Dr Dennis O’Connor, Ms Amy Clark, Ms Narelle McPhee, Mr Ayooluwatomiwa Oloruntoba, Prof Monika Janda |
| **Location**  | [Site] |

**Consent Agreement**

I have read the Participant Information Sheet.

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 understand that I will be given a signed copy of this document to keep.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Monash Universityconcerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| I consent to the (**optional**) use of my non-identifiable images for publication | **☐** | **☐** |
| I consent to the **(optional)** use of non-identifiable images of my skin lesions, including biopsy and histology images where applicable, in future research projects related to this study or within the same general area of research. | **☐** | **☐** |

**Declaration by Participant – for participants who have read the information**

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |   |  Date |  |  |
|  |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

|  |
| --- |
|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

**Form for Withdrawal of Participation -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | TRialHub tELetriAge pilot studY |
| **Short Title** | RELAY |
| **Project Number** | 88766 |
| **Project Sponsor** | Alfred Health |
| **Coordinating Principal Investigator** | Assoc Prof Victoria Mar |
| **Site Principal Investigator** | [insert site PI] |
| **Associate Investigator(s)** | Dr Ken Ip, Dr Maithili Sashindranath, Assoc Prof Chris McCormack, Dr Michelle Goh, Dr Ryan Toholka, Dr Dennis O’Connor, Ms Amy Clark, Ms Narelle McPhee, Mr Ayooluwatomiwa Oloruntoba, Prof Monika Janda |
| **Location** | [Site] |

The study doctor and relevant study staff will not collect additional personal information from you after you withdraw, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. If you do not want them to do this, you must tell them before you withdraw from the research project.

If further photography is required or a biopsy is recommended, withdrawal of consent prior to these being taken will exclude them from input into the database as part of the research project.

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with [Insert Site].

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

|  |
| --- |
|  |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

|  |
| --- |
|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.