PATIENT INFORMATION SHEET
THE IMAGE STUDY

What is a clinical trial?

A clinical trial involves research using volunteers (also called participants) that is intended to add to medical knowledge. Participants receive specific new medical treatments (or interventions) which are then compared to a standard one that is already available, to a placebo, or to no intervention. When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different than available alternatives (including no intervention). The investigating doctors try to determine the benefits and harms (if any) of the intervention by measuring certain outcomes in the participants. Adapted from ClinicalTrials.gov

What is the IMAGE Study?

The IMAGE Study (Melanoma surveillance photography to improve early detection of melanoma) tests whether an advanced medical imaging technology called Melanoma Surveillance Photography (MSP), in addition to usual care, helps to improve outcomes compared to usual care alone.

Your participation is voluntary

Participation in this research is voluntary. If you do not want to take part, you don't have to. You will continue to receive the best possible care whether or not you take part.
If you decide you wish 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 have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

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

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.

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. 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 would like to withdraw, but are still happy for study staff to contact you and collect information about your skin checks and biopsy results, please let your study doctor know. 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 join the research project.

Background Information

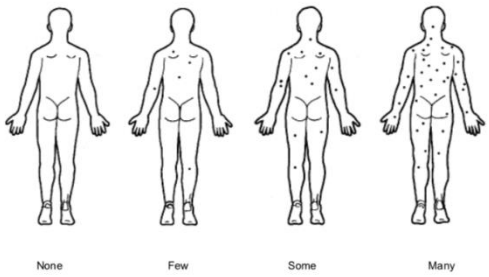
Why is it important to do this study?
Melanoma is the 3rd most common cancer in Australia. Early detection of melanoma is important because thinner melanomas are associated with lower risk of spread to other parts of the body. After being diagnosed with melanoma, both patients and doctors can become more anxious about other skin lesions, and this often leads to a high number of biopsies of benign (harmless) lesions.

Melanoma surveillance photography (MSP), is a comprehensive surveillance method. To date, there is insufficient evidence that MSP improves outcomes. Currently, melanoma surveillance photography is not used routinely during skin examinations as part of 'standard care'. MSP is not reimbursed by Medicare and is often costly. This project will test whether people who are monitored with MSP, have fewer benign lesions removed or sampled, compared to those who do not have MSP. This trial will help provide the information needed by the Medical Services Advisory Committee (MSAC - the committee advising the Australian Government on the public funding of new medical services), to decide if MSP should be covered by Medicare.

Eligibility Criteria

Who is eligible to participate?
The IMAGE study is currently recruiting patients with a diagnosis of melanoma within the last 6 months (186 days). Your doctor will be discussing the IMAGE study with you because you have recently been diagnosed with your first melanoma and you may be eligible to participate - if other criteria are also met.
If you are:

- *Aged 18 years or older at date of diagnosis of your first melanoma*
- *Able to provide consent, complete questionnaires, and attend a local study site for MSP*
- *Able to be referred for total body photography (you will need to undress to underwear and stand for imaging)*
- *Have "some" or "many" moles according to the right hand side diagram; and*
- *Currently living in Australia and have no plans to move overseas within the next 3 years*



you may be eligible to participate in the IMAGE study.
There are certain types of melanomas that will mean you are not eligible, even if all criteria above have been met. You doctor will discuss whether they are relevant for your circumstances. This sheet provides a brief outline of the study but not all information participants will need to consider when thinking about joining the study.

What's MSP?

What's involved in melanoma surveillance photography (MSP)?
MSP combines 2D or 3D total body photography (images of the whole skin surface) with digital dermoscopy (close-up photos of individual skin lesions) to closely monitor lesions and is performed at set intervals – annually in the IMAGE study.
New technology is available that enables rapid, radiation-free total body imaging. These images can be reviewed by your usual doctor to monitor the appearance of skin lesions over time and may help to improve detection of malignant lesions – and also to better differentiate malignant from benign lesions.

IMAGE Study Groups

Will I definitely have MSP if I participate?
No – not all participants will receive MSP. If you decide to participate, you will be allocated to one of two possible groups:

- An **INTERVENTION** Group, where all participants receive MSP in addition to standard care routine monitoring; or
- An **ACTIVE-CONTROL** Group, where all participants continue with standard care routine monitoring without the use of MSP. We will invite you back at the end of the study (after three years) to receive one session of 3D total body photography if you wish. The cost of this 3D photography will be free of charge.

Next Steps

We encourage you to talk to your usual doctor, trusted friends and family while you decide whether or not you'd like to participate. You will be given a document containing the full information on the study which needs to be read and tells you about the test involved in the trial. Knowing what is involved will help you decide if you want to take part in the research.
If you have questions or want further information, you are welcome to contact the Lead Investigator doctor or the IMAGE Research Staff at your nearest study site. Your usual doctor can provide contact details for you or, alternatively, you can visit the IMAGE website at www.masc.org.au/recruiting-trials/ to find contact details.