



## **IN VIVO CONFOCAL MICROSCOPY STUDY OF THE SKIN AND MUCOSA RESEARCH IMAGING DATABASE**

### **INFORMATION FOR PARTICIPANTS**

#### **Introduction**

You are invited to contribute your health information to a database of patients receiving medical treatment for melanoma and other skin tumours at the Poche Centre, Melanoma Institute Australia (MIA) and at the Sydney Melanoma Diagnostic Centre, Royal Prince Alfred Hospital.

It is hoped that information collected on this database will help researchers to better understand the nature of melanoma and skin cancers and assist in developing future clinical research.

The database is being managed by Dr Pascale Guitera, a dermatologist and Associate Professor at the University of Sydney. It is being overseen by the MIA Research Committee which includes clinicians, pathologists, medical scientists and an experienced data manager.

#### **Background**

Reflectance confocal microscopy (RCM) is an imaging device that uses a weak laser light and a sophisticated lens to image below the surface of the skin. This type of imaging can visualize individual cells that make up your skin including cancer cells.

The procedure may involve placing a disposable plastic ring on the skin to stabilise the picture it has taken. If necessary the hair on and/or around your lesion(s) will be trimmed, and a drop of gel will be applied. The procedures will take 10 minutes per lesion. You will be able to see the pictures of your lesion(s) on the computer screen as the procedures are being done. This is part of your routine care.

#### **Risks**

There are no known risks or disadvantages of taking part in this project.

#### **Contributing to the database**

If you agree to contribute to this database, you will be asked to sign the Participant Consent Form.

Relevant information will then be obtained from your medical record and stored in the database. This will include your name, gender, date of birth, clinical details, medical history and the number associated with the RCM images. The database will provide a link between the images and your history. The images obtained from the RCM will not be stored on the database.

As indicated above, in the database your health information will be identified with a number to protect your privacy. Your name will be recorded in connection with this number, but information about you will only be linked to your number. The information will always be treated confidentially, and only Dr Pascale Guitera, (the database custodian), and authorised researchers who have access to it.

The results of research conducted using the database may be presented at a conference or in a scientific publication, but individual patients will not be identifiable in such a presentation.

If you agree, the information collected for, used in or generated by this research may be used for future research with the approval of a Human Research Ethics Committee. The Human Research Ethics Committee will determine whether, or not, your consent should be obtained at that time for a particular research project. It will not be possible to provide you with feedback about the findings of potential future research.

### **Benefits**

While we intend this database to be used to further medical knowledge and to improve treatment of melanoma and skin cancer in the future, it may not be of direct benefit to you.

### **Costs**

Contributing to this database will not cost you anything, nor will you be paid.

### **Voluntary Participation**

Contributing to this database is entirely voluntary. You do not have to do so. If you do, you can withdraw your health information 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.

### **Further Information**

When you have read this information, Dr Guitera will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact her on 02 9911 7240.

This information sheet is for you to keep.

### **Ethics Approval and Complaints**

The establishment of this database has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health Network. Any person with concerns or complaints about it should contact the Executive Officer on 02 9515 6766 and quote protocol number X15-0392.