**Autoantibody Biomarkers for Melanoma Detection**

Dr. Pauline Zaenker, Prof. Mel Ziman, A/Prof. Elin Gray, Dr. Johnny Lo, Ms. Anna Reid, Dr. Christopher Quirk, Ms. Kitiya Dufall, Dr. Lester Cowell, Ms. Michelle Pereira, Ms. Paula Van Miert, Mr. Mark Lee, Dr. Ashleigh McEvoy, A/Prof. Prasad Kumarasinghe, Mr. Michael Morici, Mr. Mark Hanikeri, Dr. Jonathan Chan, A/Prof. Helmut Schaider, Dr. Michell Stark, Dr. Tony Caccetta, Dr. Austen Anderson, Dr. Stephanie Weston, Dr. Rachael Foster, Dr. Phillip Cantwell

**Please take time to read the following information carefully and discuss it with your friends, family, dermatologist and general practitioner if you wish. Ask us any question if some part of the information is not clear to you or if you would like more information. Please do this before you sign this consent form.**

**Edith Cowan University (ECU) contact persons:**

Should you have questions about the study you may contact:

Dr. Pauline Zaenker Phone No. (08) 6304 2783 E-mail: p.zaenker@ecu.edu.au

Prof. Mel Ziman Phone No. (08) 6304 3640 E-mail: m.ziman@ecu.edu.au

This study has been registered with the Australian New Zealand Clinical Trials Registry (ANZCTR request number 377786).

All study participants will be provided with a copy of the Information Sheet and Consent Form. They may keep the information sheet for their personal records.

You may decide to be in the study or not take part at all. If you do decide to take part in this study, you may stop at any time by providing us with a written note. However, before you decide, it is important that you understand why this research is being done and what it will involve. Whatever your decision, this decision will not lead to any penalty or affect your regular medical care or any benefit to which you are otherwise entitled.

ECU is responsible for the research project which it is conducting with the support of various clinicians and hospitals.

**The following information sheet will explain the study and will include:**

* Why this trial might be suitable for you
* The possible risks (side-effects) and benefits of the new test
* The type, frequency and risks of any medical tests or procedures required by the trial
* The nature of your participation
* Your rights and responsibilities
* Who is funding this study

**What is the purpose of the study?**

This study is a research project in which we are investigating autoantibodies, markers of the body’s immunological response in the peripheral blood of patients with melanoma skin cancer relative to these markers in healthy volunteer blood and in tumour tissue. The levels of autoantibodies in blood will be measured by a blood test that we are currently developing. It is anticipated that changes in these markers may be used to identify changes in the blood of patients that are indicative of tumour presence (diagnostic).

Participants with suspected cutaneous melanoma will be invited to participate in the study. Additionally, we will invite some patients with other cancer types and autoimmune diseases to provide a blood sample for this study to evaluate whether the identified autoantibodies are melanoma specific.

We will ask your consent to collect your blood and store this in the freezer for laboratory experiments related to the identification of autoantibodies in your blood. We may also ask your consent to access a small amount of your biopsy/tumour tissue stored at Pathology Centres that is in excess of that taken for routine diagnosis. We may utilise this tissue to compare the expression of proteins and the presence immune cells in the tumour with the autoantibody types and levels in your blood.

To validate our test and determine the longevity of the autoantibody levels in blood, we are asking for your permission to let us contact you approximately 12 months after your initial blood donation to provide us with a follow up sample, but this of course voluntary and you may decide not to provide this additional blood sample.

**Why is this study suitable to me?**

You have been invited to participate in this study because you have a suspicious lesion that is thought to be a melanoma or you recently have been diagnosed with other early stage types of cancer or an autoimmune disease.

**How long will I be in this study?**

The study will be conducted over a three-year period. However, as a participant, you will be asked to provide a once-off blood sample prior to the partial or complete surgical biopsy for your suspected melanoma. Some participants may be asked for a follow up sample after their initial blood donation.

As a participant you may also be asked to provide consent for us to access a small amount of your tumour tissue from tissue biopsied as part of routine diagnosis from a sample stored at Pathology Centres following diagnosis.

**What will happen if I decide to be in this study?**

If you agree to participate you will be asked to provide a blood sample before the partial or complete surgical removal of your suspicious lesion.

The amount of blood required for this study is small (approximately 12 ml). Blood will be drawn into 2 x 6 ml SST blood tubes, for isolation and storage of the serum.

Generally, you will not be contacted following your blood donation, however if you have given permission for the researchers to contact you for a follow up sample by ticking the “Yes” box on the consent form and have therefore provided contact details, the researchers will get in contact via a letter or e-mail approximately 12 months after your initial blood donation. The collection of this additional blood sample is voluntary and you may decline to provide one by ticking the “No” box on the consent form or you may decline verbally or in writing when asked by the researchers. Whether you choose to provide the initial or additional blood sample will not influence your routine clinical assessment or treatment. The additional blood collection will occur at either the clinician’s consultation rooms or at ECU by trained phlebotomists or alternatively at pathology specimen collection points at hospitals and centres associated with the collaborating clinical practice.

If you require general information about the research at any time, you are able to contact the researchers should you wish to do so. Contact details are provided in the information sheet.

Your blood will be tested relative to blood from other participants and in some cases to your tissue (biopsy) samples. Your samples are only identifiable by a coded number, the researchers performing the tests will not know which samples are yours.

Your samples will be stored in locked freezers in secure research laboratories during the research study and will be discarded after a minimum of 7 years after completion of the study or prior upon your written request.

**Are there any reasons I should not be in this study?**

Certain conditions will make you exempt from this study. These include: being under the age of 18 years, recent surgery (in the last three months) or having a cognitive disability. The clinical staff assisting with this study will discuss the research with you in detail and will ensure that this trial is both safe and appropriate for you.

**What are the costs to me?**

There will be no additional costs over and above your visits to the doctor. Blood will be taken at the clinic, or you may be asked to visit a pathology centre before you visit your doctor for treatment and /or at follow-up visits. You do not have to pay for the collection of the blood sample. In some cases, the blood may also be collected at ECU in Joondalup by trained phlebotomists. Tumour/biopsy tissue may be obtained through your clinician and pathology centres.

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

There is no direct benefit to you for taking part in this study; however, this test may benefit the diagnosis and treatment of future patients. The research will not provide you with any detailed information about your health.

Donation of your sample may assist researchers to provide a more detailed and specific diagnosis of cancer for future patients.

**How will my safety be ensured?**

In this study, the samples that you provide are blood samples and you will also be asked to provide permission to access a small quantity of your tissue sample(s). There is very little risk to you as only a small volume of blood is required for the test and the tissue has already been removed during diagnostic surgery. Please do not hesitate to contact the study coordinator or your doctor in relation to any adverse effects you think you are experiencing.

The study may produce results that are clinically informative. Your clinician will be notified of your result and additional clinical tests will be performed if your doctor feels it is in your best medical interest. When you stop participation in the study you will be clinically assessed as you were at the beginning of the study.

**What alternatives do I have to going on this study?**

Participation in this study is voluntary and choosing not to take part will not affect your treatment. Your treatment will continue in the same manner whether you decide to participate in the study or not.

**What are the possible side effects, risks and discomforts of taking part?**

In this study, only a small volume of blood is taken (12 ml) at one or more of your scheduled visits so there is very little risk to you in this procedure. You may suffer a small amount of discomfort when you donate the blood or tissue sample, like the feeling of a pin prick or bruising.

The likelihood of side effects from donating blood or tissue is small, around 1 in 100. However, should you suffer any side effects please tell your doctor immediately about any new or unusual symptoms that you get.

**What if new information comes along during the study?**

Sometimes new information about a blood test becomes available as a study progresses. You will be told about any information that could be important to you.

**What happens at the end of the study?**

At the end of the study your visits to your doctor will continue and your treatment will not be affected by the outcome of the research.

**Will my taking part in this study be kept confidential?**

The researchers will need to collect data about you, which may be sensitive, such as your relevant health information. This includes clinical records relating to the diagnosis and treatment of your tumour. The researchers may also need to get some of your health information from other health service providers, e.g. another hospital, pathology laboratory, radiographer, GP or other medical specialist. The researchers may use your contact information to inform you about an additional blood collection if required, but only at the approval of your doctor.

Any personal or health information will be kept private and confidential. It will be stored securely and only authorised persons, who understand it must be kept confidential, will have access to it. Your study details will be given a number so that your identity will not be apparent. During the study, the trial records will be kept by Dr. Zaenker, the study Principle Investigator at The School of Medical and Health Sciences at ECU, and in a locked archive for at least 7 years after data publication, and will be destroyed by incineration thereafter.

Authorised representatives of the researchers, the investigating doctors, the Hospital or University Human Research Ethics Committees, Research Governance and other regulatory bodies may require access to your de-identified study records for study procedures and/or for data analysis. Your sample may be sent to the study collaborators in other states or countries for analysis, however your sample will be identified by a sample number only, and your name and personal details will not be provided. In all cases when dealing with your sample, researchers are required to comply with privacy laws that protect you.

The result of the research will be made available to other doctors through medical journals or meetings, but you will not be identifiable in these communications.

ECU may seek to further develop the research and blood test in conjunction with a separate company established for this purpose. In this case, your de-identified health information may need to be disclosed to this company in order for your participation in the study to continue. Your personal and health information will remain private and confidential, stored securely and will only be available to authorised persons who need to know the information for the purposes of the study.

**Do any researchers have a personal interest in the study?**

Certain researchers responsible for the invention of the blood test may have a perceived personal interest in the study as these researchers may be entitled to a percentage of profits received as a result of the commercialisation of the research and blood test (if any).

**Will I find out the results of the study?**

The value of the research is not known at this time. Therefore, researchers will not give out individual research results to you.

**Who has reviewed the study?**

The Edith Cowan University Human Research Ethics Committee have reviewed this study and have given approval for conducting this research trial. In doing so this study conforms to the principles set out by the National Statement on Ethical Conduct in Research involving Humans and according to the Good Clinical Practice Guidelines.

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

**Autoantibody Biomarkers for Melanoma Detection**

Dr. Pauline Zaenker, Prof. Mel Ziman, A/Prof. Elin Gray, Dr. Johnny Lo, Ms. Anna Reid, Dr. Christopher Quirk, Ms. Kitiya Dufall, Dr. Lester Cowell, Ms. Michelle Pereira, Ms. Paula Van Miert, Mr. Mark Lee, Dr. Ashleigh McEvoy, A/Prof. Prasad Kumarasinghe, Mr. Michael Morici, Mr. Mark Hanikeri, Dr. Jonathan Chan, A/Prof. Helmut Schaider, Dr. Michell Stark, Dr. Tony Caccetta, Dr. Austen Anderson, Dr. Stephanie Weston, Dr. Rachael Foster, Dr. Phillip Cantwell

**Participant Name:**

**Date of Birth:**

**Contact details:**

1. I have been given clear information (verbal and written) about this study and have been given time to consider whether I want to take part.
2. I have been told about the possible advantages and risks of taking part in the study and I understand what I am being asked to do.
3. I have been able to have a member of my family or a friend with me, if necessary, while I was told about the study. I have been able to ask questions and all questions have been answered satisfactorily.
4. I know that I do not have to take part in the study and that I can withdraw at any time during the study without affecting my future medical care.
5. I agree to take part in this research study and for the data obtained to be published provided my name or other identifying information is not used.
6. I provide consent for my clinical details relating to the tumour or other autoimmune disease diagnosis and history to be made available to the researchers.
7. I provide consent for the researchers to access a small sample of blood (12 ml) and tissue that is additional to that required for diagnosis.
8. I provide consent for my peripheral blood or tissue to be used in laboratory experiments or stored for our future research where appropriate.
9. I understand that I will not receive any information about the results of my test personally but am aware that my clinician will be notified of any results which may be clinically informative and that the treating clinician will perform additional tests where necessary.
10. I provide consent for my samples to be sent to researchers and biotechnology companies locally, nationally and internationally for collaborative studies, or be used in experiments with the aim to produce a blood test to improve patient diagnosis and monitoring.
11. I understand that my sample may be used for development of commercial testing kits by ECU melanoma researchers in collaboration with companies internationally, however no personal identifying information will be provided with my sample. I will not receive any profits potentially generated from participation in this study.
12. I understand that ECU may seek to further develop the research and blood test in conjunction with a separate company and that my de-identified health information may need to be disclosed to this company in order for my participation in the study to continue. I consent to this disclosure of information.
13. I provide consent for researchers to obtain my contact details and to contact me should additional blood samples be required? Yes No

If you are unclear about anything you have read in the Participant Information Sheet or this Consent Form, please speak to your doctor before signing this Consent Form.

**Name of Participant Signature of Participant Date**

**Name of Investigator Signature of Investigator Date**

The ECU Human Research Ethics Committee has given ethics approval for this study. If you have any concerns, you can contact the ECU Human Research Ethics Committee: Phone (08) 6304 2784.

**All study participants will be provided with a copy of the Information Sheet and Consent Form for their personal records.**