Hollywood Private Hospital
Part of Ramsay Health Care

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PARTICIPANT INFORMATION SHEET

Clinical Implementation of Personalised Medicine for West Australian Cancer Patients

Researchers

Prof. B Amanuel	Prof. M Millward	Dr. A. Hasani
A/Prof. C Robinson	Prof. A Nowak	Prof. A Khattak

Please take time to read the following information carefully and discuss it with your friends, family 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 the consent form.

What is this study about?
Genes are like instructions telling the body how to function, grow and develop. Cancers arise due to errors in genes which means some of the body's cells do not function correctly and a cancer grows. These errors are often called 'mutations' or 'variants'.

When a patient is diagnosed with cancer, some routine pathology tests are carried out to help doctors diagnose the cancer and decide how to treat the patient. In this study we are trialing a new type of test, called Comprehensive Next Generation Sequencing (NGS) that will provide your doctor with more detailed information about the gene mutations that are present in your cancer. This is sometimes referred to as 'Comprehensive Genomic Profiling' or 'Personalised Medicine'.

Knowing this detailed information will enable a more accurate diagnosis of your cancer and could match you to a more suitable treatment that is specific for your own cancer profile. It may also identify a clinical trial that is suitable for cancers with the mutations that have been found. The new test includes important findings from the latest medical research and clinical trial data, so that your treatment will be based on the most up-to-date scientific evidence available.

If you provide consent to participate in this study, your cancer samples will still undergo the normal routine tests to determine your diagnosis, prognosis and/or treatment strategy; your oncologist will explain the routine tests that are relevant to you.

What is the purpose of this study?
The purpose of this study is to investigate the feasibility and the benefits of Comprehensive Genomic Profiling as a routine test in the clinical setting.

The study will be undertaken by experts at all stages in the clinical workflow - from referral to reporting of results back to the treating doctor - so that we can optimise the process and best assess the clinical benefit for patients.

The health economic value of this testing for the Western Australian Health Service will also be assessed.

Who is funding this study?
This study is funded by the WA Department of Health and the Community Health and Hospital Programme.

Contact persons:
Should you have questions about the study you may contact:

Dr B Amanuel 6457 2603
Dr C Robinson 6457 1930

What sort of tissue or blood samples are required?
We will require a portion of the cancer tissue or blood sample that has already been collected as part of the routine procedure for cancer diagnosis and treatment.

How will my tissue or blood samples be collected?
The samples will be collected as part of the routine diagnostic procedure. Thus, you will not need to undergo any additional procedures outside of the normal clinical management of your cancer.

Where will my tissue or blood samples be stored?
The samples will be stored at PathWest Laboratory Medicine, QEII Medical Centre. This is routine procedure for all diagnostic samples that are tested by PathWest.

How long will my tissue or blood samples be stored for?
The cancer tissue specimens obtained for routine diagnostic purposes can be stored long term and are usually archived indefinitely by the pathology service provider in case reanalysis is necessary in the future. This is as per PathWest and Department of Health policies.
The cancer tissue or blood samples assigned for the research will usually be used up by the tests and thus storage will not apply. However, any excess research sample will be stored for short term use, such as repeat experiments required within this project. There will be no long term storage for unspecified use.

Will I get my test results?
You will not directly receive the test results in a report because the test is still under development and is not yet approved by the National Association of Testing Authority for reporting purposes. Instead, your oncologist or treating doctor will be given the test report and they will discuss the results with you and any impact the molecular profiling has on your cancer treatment options

Other Findings
Very rarely, the test may find something unrelated to your cancer, called an incidental finding. Your doctor will discuss this with you if this is found and you can choose whether you want to receive more information. If there is an incidental finding of a mutation associated with a risk of hereditary disease, then you can be referred for genetic counselling if you wish. A genetic counsellor can help you consider any implications this test result may have for you or your family members.

How will my privacy be maintained?
Your results and genomic information from the test will be stored securely using systems that meet Australian and international privacy and security standards and laboratory guidelines.
The data generated in this project will abide by the normal rules of privacy for any health records and will be identifiable by doctors and pathologists for clinical purposes, however any data analysis for the purpose of drawing conclusions from the study will be non-identifiable. Further, your identifiable information will not be included in any publications or presentations arising from the study.

It is important to note, as with all health information kept about you, that there may be circumstances where disclosure of your health information as kept for this study will be required by law, for example, as a result of a court order.

Further information on how your information is kept private and secure can be sought from your healthcare provider.

Is there a health benefit if I participate?
Your cancer samples will still undergo the routine testing ordered by your doctor or the pathologist, however, this new test will provide more detailed information that may further refine your diagnosis or identify a more suitable treatment options for you. This could have a benefit for you if there are no other standard treatment options available. It may also enable you to participate in clinical trials, by identifying available trials that match your cancer type or mutations.

Is there a consequence if I choose not to participate?
If you choose not to participate, there is no consequence. You will continue to receive the routine testing currently used for your cancer management.

What if I change my mind later?
You may withdraw from the study at any time and samples may be destroyed upon request. Please contact Dr. C Robinson or Dr. B Amanuel, PathWest, QEII Medical Centre, phone 6457 1930 / 6457 1862 to arrange this.

How will the sample be disposed of when it is no longer required?
Most samples are used up by the test, however any remaining samples that are no longer required will be disposed of at the end of the study according to the approved procedure for biological specimens. If you wish to withdraw from the study and have your samples destroyed, the DNA or RNA extracted from cancer tissue will be disposed of according to the approved procedure for biological samples.

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CONSENT FORM

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A/Prof. C Robinson	Prof. A Nowak	Dr. A Hasani

Participant Name: _____

Date of Birth: _____ **UMRN:** _____

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

I have been given information, both verbally and in writing, about this study and having had time to consider it, I am now able to make an informed decision to participate.

I have been told about the potential benefits and known risks of taking part in this study and I understand what this means to me.

I have been given the opportunity to have a member of my family or a friend with me when this study was being explained to me. I have been able to ask questions and have had all my questions answered.

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.

I understand that participating in this study does not affect any right to compensation, which I may have under statute or common law.

I accept that by taking part in this research, that any information obtained about me during the study may be published, provided that my name and other identifying information are not used.

Name of Participant	Signature of Participant	Date
Name of Treating Doctor	Signature of Treating Doctor	Date

The Sir Charles Gairdner and Osborne Park Health Care Group Human Research Ethics Committee has given ethics approval for the conduct of this study. If you have any ethical concerns regarding the study you can contact the Executive Officer of the Sir Charles Gairdner and Osborne Park Health Care Group Human Research Ethics Committee on (08) 6457 2999 or HREC.SCGH@health.wa.gov.au.

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