Sir Charles Gairdner Hospital

PARTICIPANT INFORMATION SHEET (GENETIC)

Clinical implementation of personalised medicine

Researchers

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Dr C Thomas
Dr Y Leung
Dr P Robbins
Dr C Stewart
Dr S Raftopoulos
Dr G van Hazel
Dr T Ferguson
Dr T Giardina
Dr M Thomas
Dr T Humphries
Dr P Lau
Dr N Mesbah Ardakani

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.

Who is funding this study?
This study is funded by the WA Department of Health and 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 is the purpose of this study?
This project will investigate the feasibility of the use of two new assays called Next Generation Sequencing (NGS) and RNAseq in the clinical setting. These assays are designed to detect gene abnormalities (mutations) that occur in cancer tissue. Knowing this information helps clinicians in diagnosis and deciding on the right cancer treatment. These tests do not target the mutations that indicate there is a risk of a hereditary disease.
We have developed assays that are highly suitable for analysis of different types of cancer including, but not limited to, lung cancers, gastrointestinal cancers, brain cancers, gynaecological cancers, melanoma and rare cancers such as sarcoma. The analysis includes important findings from the latest research data.

Patient's cancer samples will still undergo the routine tests to determine their diagnosis, prognosis or treatment strategy. However, the new tests could help clinicians to identify a new treatment option for cancer patients for whom all standard options have been exhausted. The tests could also enable entry into a clinical trial.
The study will be undertaken by experts from all stages in the routine workflow so that we can optimise the process and fully assess the clinical benefit. The economic value for the health service will also be assessed.

What sort of tissue or blood sample/s are required?
We will require a portion of the cancer tissue and/or a blood sample. We will use the tissue sample that is already collected as part of the patients' routine diagnostic procedure. For some patients we will require a blood sample for the analysis.

How will my tissue or blood samples be collected?
The tissue samples will be collected as part of the patients' routine diagnostic procedure. Thus, the patient will not need to undergo any additional procedures outside of their normal clinical management. For the blood sample, the patient will be provided with a pathology request form during their doctor consultation and will be asked to visit a pathology collection centre for the blood sample to be collected.

Where will my tissue or blood samples be stored?
The samples will be stored at PathWest Laboratory Medicine, QEII Medical Centre, as per 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 diagnostic purposes can be stored long term and are usually archived indefinitely 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 assays 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?
Patients will not directly receive the test results because the test is still under development and is not yet approved by the National Association of Testing Authority for reporting purposes. Patients' Oncologist or other clinician will be given the test result. If there is an incidental finding of a mutation associated with a risk of hereditary disease, then the clinician will be notified and the patient will be referred for genetic counselling.

How will my privacy be maintained?
The data generated in this project will abide by the normal rules of privacy for any health records and will be identifiable by clinicians and pathologists for clinical purposes.
However, any data analysis for the purpose of drawing conclusions from the study will be non-identifiable. Furthermore, patients will not be identified in any publications or presentations arising from the study.
No information about family members is required for this project.

Is there a health benefit if I participate?

Patients will still undergo the routine testing for diagnosis and treatment selection, however, the new tests may provide information that further refines diagnosis or suggests alternative treatment options. This could have a benefit for patients for whom all other standard treatments have been exhausted. It may also enable patients to participate in clinical trials.

Is there a consequence if I choose not to participate?
There is no consequence for patients who choose not to participate, as all patients will receive the routine testing currently used for their cancer management.

What if I change my mind later?
Participants 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?
DNA or RNA extracted from cancer tissue will be disposed of according to the approved procedure for biological samples.
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.

CONSENT FORM
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Dr T Ferguson
Dr T Giardina
Dr M Thomas
Dr T Humphries
Dr P Lau
Dr N Mesbah Ardakani

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.

1. 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.

2. 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.

3. 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.

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

6. 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.