



KING EDWARD MEMORIAL HOSPITAL PARTICIPANT INFORMATION SHEET (GENETIC)

Clinical implementation of personalised medicine

Researchers

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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 Program

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 the assays that are highly suitable for analysis of different types of cancer including, but not limited to, lung cancer, 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 or blood that is already collected as part of the patients' routine diagnostic procedure.

How will my tissue or blood samples be collected?

The 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.

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.

Who to contact if I have any concerns/complaints about the study or its organisation?

If you have any concerns or complaints regarding this study, you can contact the Director of Clinical Services at KEMH (Telephone No: (08) 6458 2222) on a confidential basis. Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.

Consent Form - *Adult providing own consent*

Title	Clinical implementation of personalised medicine for high priority WA cancers
Short Title	Clinical implementation of personalised medicine
Protocol Number	2016-176 v5
Project Sponsor	Not applicable
Coordinating Principal Investigator/ Principal Investigator	Dr Benhur Amanuel (CPI), Dr Cleo Robinson (PI)
Associate Investigator(s)	Prof M Millward, Prof A Nowak, Dr T Meniawy, Dr T Ferguson, Dr G van Hazel, Dr T Humphries, Dr T Giardina, Dr M Thomas, Dr C Thomas, Dr C Stewart, Dr P Robbins, Dr Y Leung, Dr P Kumarasinghe, Dr B de Boer, Dr B Wood, A/Prof S Robinson, Dr S Raftopoulos, Dr P Lau, Dr N Mesbah Ardakani.
Location	King Edward Memorial Hospital

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I understand that the results of the project may be published and/or presented in a variety of forums in such a way that I cannot be identified.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

I give permission for the storage and use of my data and samples/tissue for the purpose of:

1. this research project; Yes No
2. any closely related future research projects; Yes No
3. any future projects that may or may not be related to this research project. Yes No



I consent to be recontacted by the researchers regarding any follow-up studies

Yes No

 Name of Participant (please print)

 Signature of Participant

 Date

 Name of Witness* to Participant's signature (please print) Signature

 Date

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older

Declaration by Treating Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Treating Doctor/ Senior Researcher† (please print) _____
Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

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.