Government of **Western Australia**
Child and Adolescent Health Service

Participant Information Sheet/Consent Form - Parent/Guardian

Perth Children's Hospital

Title	*Clinical Implementation of Personalised Medicine for West Australian Cancer Patients.*
Project Sponsor	*Funded by The Community Health and Hospital Programme*
Principal Investigator	*Clinical Professor Benhur Amanuel*
Associate Investigator(s)	*Dr Annie Ryan*
Location	*Pathwest, QEII Medical Centre* *15 Hospital Avenue, Nedlands, Western Australia, 6009*

1 Introduction

This is an invitation for your child to take part in a project that will use a new test that provides your child's doctor with detailed information about your child's cancer. This extra information will help your doctor to make decisions about how to treat your child's cancer based on the latest medical findings. The project is called 'Clinical Implementation of Personalised Medicine for West Australian Cancer Patients'.

This Parent/Guardian Information Sheet/Consent Form tells you about the research project and the new test. Knowing what is involved will help you decide if you want your child to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether your child can take part, you might want to talk about it with a relative, friend or local doctor. We encourage parents to include their child in the discussion and decision to the extent that the child is able to understand. If you believe your child is able to understand what the research involves, please have your child countersign all areas requiring consent.

Participation in this research is voluntary. If you do not wish for your child to take part, they do not have to. They will receive the best possible care whether they take part or not.

If you decide you want your child to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to your child taking part in the research project
- Consent to your child having the test as described
- Consent to the use of your child's personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

The purpose of this research is to find out whether a new test that can find gene mutations in cancer specimens will enable doctors to make more informed decisions about how to treat the cancer. 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'. This research test will look for variants in genes that are known to be involved in cancer growth and which could be important for cancer treatment. It does not look at your other genes that are not involved in cancer.

When a person is diagnosed with cancer, pathology tests are carried out to help doctors diagnose the cancer type and work out how to best to treat the cancer. In this study we are trying out a new type of test, called Comprehensive Next Generation Sequencing (NGS) that will provide your child's doctor with much more detailed information about their cancer, because it looks at many more genes than the usual routine tests do. This is also often referred to as 'Comprehensive Genomic Profiling' or 'Personalised Medicine'.

It often takes a while before important new research findings are used in the clinic. In cancer we found that this can be due to a lack of understanding of the complex test results. This project aims to overcome this problem by explaining the results more clearly to your child's doctor. The test will be carried out at the PathWest pathology diagnostic laboratory, where other tests on cancer samples are already routinely carried out. We will provide a report to your child's doctor that clearly explains what the variants mean for your child's own cancer. The results will be discussed at a special multidisciplinary team meeting of expert doctors and they will make a recommendation for your child's treatment that is based on your child's test results and the latest medical findings. A report explaining the results will then be sent to your child's treating doctor, who will be able to use the information to make the best decision on how to treat your child's cancer, taking into account all of your child's circumstances.

Knowing this detailed information could mean a more accurate diagnosis of your child's cancer and it could match them to a new or different treatment. The test results may also identify a clinical trial that is suitable for your child's cancer. The new test includes important findings from the latest medical research and clinical trial data, so that your child's treatment will be based on the most up-to-date scientific evidence available.

This research has been initiated by the principal study doctor, Clinical Professor Benhur Amanuel and has been funded by the WA Department of Health and the Community Health and Hospital Programme. The research is being led by PathWest Laboratory Medicine, Western Australia in collaboration with local doctors from Perth hospitals.

3 What does participation in this research involve?

If you decide you want your child to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to your child taking part in the research project
- Consent to your child having the test as described
- Consent to the use of your child's personal and health information as described

If you provide consent for your child to participate in this study, your child's cancer samples will still undergo the normal routine tests to determine their diagnosis, prognosis and/or treatment strategy. This test is an additional test and it will use the same tissue specimen that was collected for the routine testing. There are no additional procedures for your child if they take part in this study.

What does the participant have to do?

We will require a small part of your child's cancer tissue sample that has already been collected as part of the routine procedure for cancer diagnosis and treatment. Thus, your child will not need to

undergo any additional procedures for this research and outside of understanding this information and signing the consent form, there is no action to be taken by the participant.

However, for some patients a blood sample can be used for the testing and if this is required, 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.

Additional costs and reimbursement
There are no costs to you if you allow your child to participate in this research project, nor will you or the participant be paid. The cost of the test is covered by the funding we have received to carry out the project.

Access to personal records
Personal health records are not accessed by the researchers. Doctors will have access to health records as part of their normal clinical role. Information about your child's cancer type and current or previous treatments is provided by your child's doctor and this information is presented by a doctor at a multidisciplinary meeting when the test results are discussed. This helps the doctors to make treatment recommendations based on the test results. Researchers, including scientists, pathologists and oncologists will be present at this meeting, however, information from personal health records is not stored in a research database or used for research purposes.

How will my child's privacy be maintained?
All research data generated in this project will be non-identifiable when it is analysed and when drawing the study conclusions. Any data included in presentations or publications will also be non-identifiable.

The test results will be linked to your child so that the researchers can provide your child's doctor with a pathology report explaining your child's test results in the context their cancer type. The researchers are Department of Health employees who test cancer specimens as part of their usual role in the laboratory and the normal rules of privacy for health records will apply.
Your child's identifiable information will only be available to doctors, pathologists and the relevant PathWest staff for clinical purposes. Identifiable information will not be included in any publications or presentations arising from the study. However, as with all health information kept about your child, there may be circumstances where disclosure of your child's health information as kept for this study will be required by law, for example, as a result of a court order.

All identified information will be stored securely according to laboratory guidelines, using systems that meet Australian and international privacy and security standards. Further, any data analysis for the purpose of drawing conclusions from the study will be non-identifiable.

4 Other relevant information about the research project

This study investigates the feasibility and the benefits of Comprehensive Genomic Profiling as a routine test in the clinical setting. The health economic value of this testing for the Western Australian Health Service will also be assessed. This will measure the tests' efficiency, cost effectiveness and investigate the health and economic benefits that comprehensive testing can provide to current and future Western Australians diagnosed with cancer.

The study takes place at the PathWest Molecular Anatomical Pathology Laboratory, where cancer specimens are already analysed for the purpose of diagnosis and treatment when a cancer is first found in a person. This study will optimise the process of using Comprehensive Genomic Profiling in the clinical setting and we will work closely with the local doctors so that they understand the complex data and are then able to use it to benefit their patients.

The study is undertaken collaboratively by experts at all stages in the clinical workflow. The clinical workflow begins with the participant signing informed consent with their parent or guardian and their treating doctor. Pathwest scientists then retrieve a small sample from the participant's cancer tissue and perform comprehensive testing on the DNA and RNA. The data is analysed by the scientists and

pathologists and a report is written, detailing your child's own results and explaining what they mean for your child's particular cancer.
The last stage of the clinical workflow involves pathologists and oncologists discussing the findings at a multidisciplinary meeting to make a clinical or treatment recommendation for your child that is based on the result and your child's clinical situation. After this, your child's treating doctor will be given the test report and they will discuss the results with you.

Currently, there are many public and private hospitals and cancer centres throughout Western Australia participating in this project.

5 Does your child have to take part in this research project?

Participation in any research project is voluntary. If you do not wish for your child to take part, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw them from the project at any stage.

If you do decide that your child can take part, you will be given the Parent/Guardian Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether your child can or cannot take part, or to take part and later withdraw, will not affect their routine treatment, relationship with those treating them or relationship with Perth Children's Hospital.

6 What are the alternatives to participation?

Your child does not have to take part in this research project to receive treatment at this hospital. If you decline for your child to take part, they will continue to receive the routine tests that are currently used for their cancer management, as recommended by the treating doctor. Your doctor can discuss this with you before you decide.

7 What are the possible benefits of taking part?

We cannot guarantee or promise that the participant will receive any benefits from this research as it depends on the variants that are present in your child's cancer specimen. However, this new test will provide more detailed information that may give important information about their type of cancer or identify more suitable treatment options for them. Participating in this research could have an important benefit if there are no other standard treatment options available. It may also enable your child to participate in a clinical trial, by identifying trials that match the gene variants that we have found in the cancer sample.

8 What are the possible risks or disadvantages of taking part?

This research does not involve any interventions or treatments and there are no physical risks in participating in this study. The cancer tissue sample required for this study has already been collected as part of the routine procedure for cancer diagnosis and treatment.

The purpose of this research project is to use a test on your child's cancer sample to find gene variants that are present in the cancer specimen that doctors can use to decide what is the best treatment to give. However, very rarely, the test may find a gene variant (or mutation) that is unrelated to your child's cancer, called an incidental or secondary finding. Sometimes the incidental finding may be a mutation that is associated with a risk of a hereditary disease, however, it is important to note that this test does not confirm the presence of a hereditary variant, it only raises the possibility that there may be such a variant. Further testing is required to find out if the variant is present in the germline (hereditary) as opposed to just in the tumour and this is carried out by Genetic Services WA. If this happens, your child's doctor will explain what it means for your child and family. They will also discuss the option for you and your child to be referred to a genetic counsellor, through Genetic Services, WA, who would undertake further testing to determine the risk of hereditary disease if clinically appropriate and with the patient or guardian's consent.
If you do not wish to receive information about a finding of a potential hereditary disease risk, this should be clearly stated to your child's treating doctor, who will discuss the clinical implications this

may have. You have a right to withdraw your child from this research project at any time and you should advise your child's treating doctor if you do not wish for them to participate.

This research project has no risks related to applications for future insurance or employment, as this genomic profiling test looks at your child's cancer specimen only. Incidental findings, as described above, will be dealt with by your treating doctor outside of this project.

9 What will happen to the participant's test samples?

For your child to participate in this study, we will require a small sample of your child's cancer tissue to carry out the test. This sample will be identified by a unique lab number which can be traced back to the participant.

Your child will not need to undergo any additional procedures for this project because the tissue will already be collected as part of the routine procedure for cancer diagnosis and treatment. Once a small part of this tissue sample has been taken for this study, the remaining tissue is returned to the routine pathology centre. Usually this all happens within the same laboratory (PathWest Anatomical Pathology), because this laboratory also does the routine cancer pathology testing at the major public hospitals.

The sample that we take for the test is processed into DNA and RNA, which is usually completely used up by the test and thus storage will not apply. However, any left-over sample will be kept in case any further testing is required for clinical reasons in the future. Storage will be the same as for our other clinical specimens. There will be no research use of the specimen outside of this project.

10 What if the participant is withdrawn from this research project?

If you decide to withdraw your child from this research project, you may do so at any time and samples may be destroyed upon request.

If you do withdraw consent during the research project, we will not continue to process your child's sample. You should be aware that data collected up to the time the participant withdraws may already have formed part of the research project results and therefore cannot be removed. These results are not identified and cannot be traced back to your child.

If do you wish to withdraw, please use the form provided below and contact Dr C Robinson or Clinical Professor B Amanuel, Pathwest, QEII Medical Centre, Phone (08) 6457 1930 or (08) 6457 1862.

11 What happens when the research project ends?

At the end of the study we expect to publish the findings in peer reviewed journals. The results will also be presented at conferences and shared with local doctors to benefit other West Australian people with cancer. The data may also be used by the Health Department as evidence for the development of policies about health services for West Australian cancer patients.

Part 2. How is the research project being conducted?

12 What will happen to information about the participant?

The test will produce genomic profiling data that lists the gene variants present in your child's cancer specimen. These variants are saved in a non-identified database using a unique lab number that is assigned to the specimen when it arrives at the lab. These non-identified data will be used for research analysis and access is limited to health researchers. The database will be kept indefinitely.

The specimen's unique lab number is recorded in the PathWest laboratory information system (LIS) under the participant's pathology records, as is required for all clinical specimens that are received at PathWest. Therefore, the data can be traced back to the participant if necessary (re-identified), but

only PathWest staff who have access to the PathWest LIS are able to do this. This would occur for clinical purposes and not for research purposes.

A second non-identifiable research database that uses the unique lab number will include additional participant information as follows:

- Cancer type
- Participant age and sex
- Ranking of the clinical significance of the variants detected
- If the current diagnosis or prognosis was changed as a result of the test (Yes/No)
- If a variant with resistance to treatment was found (Yes/No)
- If potential new therapy(ies) were identified (Yes/No)
- If a potential clinical trial was identified (Yes/No)
- If the participant's treatment changed as a result of the test

The final test report that is provided to the treating doctor is identifiable and may be kept as part of the participant's medical health records as per the procedure at the treatment centre. It will not be available through the government electronic health records system (MyHR) or other systems used by hospitals for the sending of results.

The final test reports are also stored at the PathWest Molecular Anatomical Pathology laboratory in a secure laboratory information system (software) which can only be accessed by approved research investigators as determined by the study Principal Investigator. These reports are kept because they could contain clinical information that is important at a later stage in the participant's cancer journey. These reports are identifiable and are not used for research purposes. They are only viewed by health service providers for clinical purposes. They abide by the same rules of privacy that apply to any health records and the reports for the routine pathology tests that this lab undertakes. These reports will be kept indefinitely and in accordance with health policies.

By signing the consent form, you consent to the study doctor and relevant research staff obtaining personal information from your health records as described above. Any information obtained in connection with this research project that can identify the participant will remain confidential and securely stored. It will be disclosed only with your permission, or as required by law. Information about participation in this research project may be recorded in the participant's health records.

It is anticipated that the results of this research project will be published in medical journals and presented at scientific meetings or conferences. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified.

13 Complaints

If the participant has any complaints as a result of this research project, you should contact the study lead investigator Clinical Professor B Amanuel, Pathwest, QEII Medical Centre, or the Human Research Ethics Committees at Sir Charles Gairdner Hospital and Perth Children's Hospital (Children and Adolescent Health Service). Contact details are provided in Section 16 - Further information and who to contact.

14 Who is organising and funding the research?

This research is conducted by Anatomical Pathology, PathWest Laboratory Medicine WA in collaboration with Perth Children's Hospital. The Lead Investigator is Clinical Professor Benhur Amanuel and the Perth Children's Hospital site Principal Investigator is Dr Annie Ryan.

15 Who has reviewed the research project?

This research project was reviewed and funded by the WA Department of Health and the Community Health and Hospitals Programme (CHHP).

In addition, all research in Australia that involves humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This research project has been reviewed and approved by the Sir Charles Gairdner Hospital HREC (lead HREC for the project).

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research, 2007, (Updated 2018).* This statement has been developed to protect the interests of people who agree to participate in human research studies.

16 Further information and who to contact

If you would like any further information about this project, please contact Dr B Amanuel. For matters relating to research at the site at which the participant is taking part, please contact Dr Annie Ryan.

Complaints contact persons

Name	*Clinical Professor Benhur Amanuel*
Position	*Lead Investigator - Pathwest, QEII Medical Centre*
Telephone	*(08) 6457 1862*
Email	*Benhur.Amanuel@health.wa.gov.au*

Name	*Dr Annie Ryan*
Position	*Principal Investigator - Perth Children's Hospital*
Telephone	*(08) 6456 2222*

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	*Children and Adolescent Health Service*
Position	*Research Governance Officer*
Telephone	*(08) 6456 5529*
Email	*CAHS.RGO@health.wa.gov.au*

Reviewing HREC name	*The Sir Charles Gairdner Osborne Park Health Care Group (SCGOPHCG) Human Research Ethics Committee*
Position	*HREC Research Officer*
Telephone	*(08) 6457 2999*
Email	*SCGH.HREC@health.wa.gov.au*

If you have any questions or concerns that you would like to discuss with someone who is not on the research team, you may call the Executive Director Medical Services via hospital switchboard on (08) 6456 2222 or you may also call the Patient/Parent Advocate via hospital switchboard on (08) 6456 2222.

Consent Form – Parent/Guardian

Title	*Clinical Implementation of Personalised Medicine*
Project Sponsor	*Funded by The Community Health and Hospital Programme*
Principal Investigator	*Clinical Professor Benhur Amanuel*
Associate Investigator(s)	*Dr Annie Ryan*
Location	*Perth Children's Hospital* *15 Hospital Avenue* *Nedlands, Western Australia, 6009*

Declaration by Parent/Guardian

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

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

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

I give permission for my child's doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Perth Children's Hospital concerning my child's condition and treatment for the purposes of this project. I understand that such information will remain confidential.

Name of Child (please print) _____

Signature of Child
(Optional: remove if not required) _____ Date _____

Name of Parent/Guardian (please print) _____

Signature of Parent/Guardian _____ Date _____

Declaration by Study Doctor/Senior Researcher†

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

Name of Study 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.

Form for Withdrawal of Participation – Parent/Guardian

Title	*Clinical Implementation of Personalised Medicine*
Project Sponsor	*Funded by The Community Health and Hospital Programme*
Principal Investigator	*Clinical Professor Benhur Amanuel*
Associate Investigator(s)	*Dr Annie Ryan*
Location	*Perth Children's Hospital* *15 Hospital Avenue* *Nedlands, Western Australia, 6009*

Declaration by Parent/Guardian

I wish to withdraw the child from participation in the above research project and understand that such withdrawal will not affect their routine treatment, relationship with those treating them or relationship with Perth Children's Hospital.

Name of Child (please print) _____

Signature of Child (Optional) _____ Date _____

Name of Parent/Guardian (please print) _____

Signature of Parent/Guardian _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the parent/guardian of the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

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

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