FORM 2 PATIENT FORM for Non Funded Oncology Gene Testing

(NOT REQUIRED FOR NSCLC PATIENTS)

BRAF and EGFR gene mutation testing using Roche cobas CE-IVD accredited tests:

PATIENT AND SAMPLE INFORMATION:

Originating Laboratory Name: _____Contact phone number_____
Block (slide) number(s)
Laboratory Request number: _____Histology Accession number:_____

Patient Name: _____ Date of Birth: _____

Address: _____ Contact number:_____

_____ _____

Requesting Doctor: _____

PATIENT CONSENT:

I understand that this test will be performed on my tumour tissue and that this may be available as the tumour specimen embedded in a paraffin block or as sections from this block. Irrespective of the form my tissue is provided in, I give permission for the tissue to be used for testing for the detection of a possible:

BRAF / EGFR* (circle as appropriate) gene mutation.

Patient Signature: _____ Date: _____

FEES and CHARGES: GST Number: 79 427 594

Not all gene mutation testing is covered under the DHB funding schedule. Unless you receive advice that it is funded from another source (and provide details with this documentation), you will be required to pay for this testing.

The appropriate payment details are provided below to enable you to make payment to Pathology Associates Ltd. **Testing is unable to commence until payment has cleared in our account** and the blocks/tissue sections of your tumour are received by Pathlab BOP. This fee does NOT include any charges that another Pathology Service may charge for the retrieval and sending of the sample to us. You will be contacted should these charges occur.

PATIENT PAYMENT:

□ **BRAF $399.00** □ **EGFR* $550.00**

TOTAL: $ _____

#Overseas requests may incur additional costs. Please contact us for prices.

Payment via CREDIT CARD:

I hereby authorise Pathology Associates Ltd to debit my credit card for payment as indicated above.

Card Type: Visa / Mastercard
Card Number: □□□□ □□□□ □□□□ □□□□
Card Expiry: □□ / □□

Name on Card: _____
Signature: _____ Date: _____

Payment via INTERNET BANKING:

Bank - BNZ **Branch** – Tauranga
Account Name - Pathology Associates Limited **Account details** – 020466 0344008 00

Please use reference- **BRAF**

ON YOUR FORM - PLEASE INDICATE METHOD OF PAYMENT

Enquiries: Dr Tim Sutton or Dr Michael Addidle
molecular.testing@pathlab.co.nz
Phone: +64 7 578 7073
Website:www.pathlab.co.nz

BRAF Participant Information Sheet

Study Title:	A comparative Analysis ROCHE Cobas BRAF Version 1 versus Version 2		
Locality:	Waikato and Bay of Plenty	**Ethics committee ref**	14/NTB/167
Lead Investigator:	Dr T Sutton	**Contact:**	07 578 7073

We are asking for your permission to use a minute quantity of tissue from the specimen of tumour of your metastatic melanoma for research. This will either be from tissue from recent surgery, or from the small amount of residual tumour we keep on file for 20 years. This will be used to help us develop a more sensitive test to determine if patients may be eligible for new drug therapy for metastatic malignant melanoma. We hope that more patients with metastatic melanoma will be able to receive medicine which may significantly prolong life. This should not affect any past or current testing you are having and there is a small chance it may be beneficial to you in suggesting a new drug that may be effective for you. We don't require any active involvement from you other than your consent.

Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 5 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

Background

Recently advances have been made in the treatment of many metastatic tumours, particularly metastatic malignant melanoma.

In particular the BRAF inhibitors are highly effective against melanomas that have a mutated BRAF gene.

Pathlab use the Cobas 4800 PCR test from ROCHE Diagnostics to test for this mutation. This is the FDA approved test for the BRAF inhibitor drug Vermurafenib. The test looks for the most common abnormalities in the BRAF gene.

Since beginning testing for this gene, it has become apparent that New Zealand has the lowest rate of mutation of this gene in the world; 25% as opposed to 48% in the United States and Europe. This means far fewer people are eligible for help from these new BRAF inhibitor drugs in New Zealand than anywhere else in the world.

One of the possibilities is that there are more mutations in the BRAF gene, but these are of rarer type that are not detected by the original test.

ROCHE, the company that makes the test are also concerned about this possibility and therefore are in the process of developing a test that will detect all the rare abnormalities in this gene.

It must also be noted that we are not sure how these tumours with rarer mutations will respond to the BRAF inhibitor drugs. It is hoped that they will benefit from these drugs.

The Study

The study is designed to compare our current method of BRAF analysis with an experimental, but similar method that looks for a number of rare mutations that may be amenable to drug therapy.

The study is being funded from Pathlab resources, with help with reagent costs from Roche diagnostics.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You are being asked to participate in this study because you have metastatic malignant melanoma, which under current best practice, should be tested for the BRAF V600E mutation, to determine if you would be likely to benefit from treatment with an anti- BRAF drug.

If you participate in this study, your sample will be tested in the usual manner and the result promptly reported to your doctor.

YOU DO NOT NEED TO PROVIDE ANY OTHER INFORMATION OR DO ANYTHING ELSE TO PARTICIPATE.

A microscopic portion of your original specimen, will be stored and when we have accumulated enough specimens it will be analysed using the new method.

The results of this testing will be sent in an entirely anonymous fashion to ROCHE Diagnostics in America for analysis. There will be no way of them identifying individual patients.

The purpose of this study is to test a new method which will look for rare mutations in the tumour that may be amenable to treatment.

I DO NOT ANTICIPATE PARTICIPATION IN THIS STUDY WILL ALTER YOUR TREATMENT. This is because the results will probably take many months to become available. However with your permission, I may discuss your results with your doctor, if I believe a new or different therapy might be useful to you following results of the testing for the study.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

I cannot foresee any significant risks involved with the participation in this study.

There is a very slight chance you might be offered different treatment on the basis of this study.

WHO PAYS FOR THE STUDY?

The study will be paid for by Pathlab. You should not incur any additional costs, apart from the time spent reading and signing this consent form.

WHAT IF SOMETHING GOES WRONG?

I cannot foresee any problem which should impinge on you as a participant in the study.

If by some totally unforeseen circumstance, you should be injured in the course of the study, you may be eligible for ACC, in addition Pathlab also carries public liability insurance.

WHAT ARE MY RIGHTS?

This is a totally voluntary study. If you choose not to participate it will in no way affect the analysis of your specimen. You are perfectly entitled to withdraw your consent at any time.

You have the right to access any information collected about you as part of this study. Any information leaving the security of the laboratory will be anonymized, so it will not be recognizable as belonging to you.

Privacy and confidentiality are adhered to at all times in this laboratory, we have a strict institutional policy.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

It is not anticipated that the study will make any difference to your treatment.

The purpose of this study is to improve future testing for melanoma. This will allow more people to have treatment in the future.

After the study is complete the biological specimens used will be returned to storage at Pathlab and stored as per the usual guidelines.

The data from the study, will be stored for at least five years. We may use some of the data for quality assurance and development of further testing within the laboratory. It will not be available externally.

The results of this study will be available when completed on the Pathlab website: www.pathlab.co.nz. We will also endeavour to have this information published in a reputable medical journal. This particular study would be anticipated to be completed within two years.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Name: Dr Tim Sutton
Telephone number: 07 578 7073
Email: tim.sutton@pathlab.co.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Consent Form

If you need an INTERPRETER, please tell us.
If you are unable to provide interpreters for the study, please clearly state this in the Participant Information Sheet

Please tick to indicate you consent to the following *(add or delete as appropriate)*

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.	Yes ☐	
I have been given sufficient time to consider whether or not to participate in this study.	Yes ☐	
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.	Yes ☐	
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes ☐	
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.	Yes ☐	
I consent to the research staff collecting and processing my information, including information about my health.	Yes ☐	
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.	Yes ☐	
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	Yes ☐	
I understand the compensation provisions in case of injury during the study.	Yes ☐	
I know who to contact if I have any questions about the study in general.	Yes ☐	
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date: