Participant Information Sheet/Consent Form – AMN

Non-Interventional Study - *Adult providing own consent*

Title	*Evaluation of stool- and blood tests for colorectal Advanced Mucosal Neoplasia*
Short Title	*Non-invasive risk stratification CR AMN/SSP*
Protocol Version Number	*3*
Coordinating Principal Investigator/ Principal Investigator	*Professor Michael Bourke*
Associate Investigator(s)	*Dr Susanne Pedersen* *Dr Farzan Fahrtash Bahin* *Dr Eric Lee* *Dr Stephen Williams* *Dr Lawrence LaPointe* *Ms Kathleen Goodrick*
Location	Westmead Hospital

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in the above titled research project. You are a potential participant in this study because you have been referred for removal of a lesion in your colon. The research project is aiming to determine whether blood and stool tests can predict the type of lesion you have in the colon.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want 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 or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want 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 take part in the research project
• Consent to the tests and research that are described
• Consent to the use of your 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?

Westmead Hospital is a referral centre for endoscopic removal of large lesions in your bowel. Many of these lesions are either imminent cancers or can become cancers within the next few years if left untreated. This is because the lesion contains cell abnormalities. There are blood and stool tests which can suggest the presence of cell abnormalities with reasonable accuracy. We seek to evaluate how useful these tests are in predicting cell abnormalities in patients such as yourself. This research has been initiated by the study doctor, Professor Michael Bourke. This analysis of the samples is being conducted by Clinical Genomics Laboratories at North Ryde.

3 What does participation in this research involve?

You have been referred to Westmead Hospital for endoscopic removal of large bowel lesion(s). You will receive separate instructions regarding bowel preparation and how the procedure is being performed. We ask your permission to obtain 3 types of tissue sample from you: 1. Blood 2. Stool 3. A small sample of your polyp and normal bowel (using mini forceps 1 mm in size to take the sample).
For the purposes of the research we need to collect a small amount of your blood and some stool.

- You will be mailed a stool collection kit which contains detailed instructions. A small amount (2mg) of stool is collected prior to your procedure using a speared probe and subsequently inserted into the specimen collection jar. The stool collection tube is placed in a pre-stamped envelop and mailed to the researchers
- Your blood is collected in two small blood tubes (9ml each). This can be done on the day of your procedure when inserting the needle in the vein to receive sedation. Alternatively you can have your blood taken prior to your procedure at a pathology collection centre as outlined in the information sheet.

We wish to repeat this process at your follow up colonoscopy 5 months following your resection to see if the values have changed once your lesion is removed. This further colonoscopy is required as part of routine care.
The study will take place over 4 years but your involvement is only whilst you have your scheduled procedures (approx 6 months).

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

4 What do I have to do?

You will be sent information on how to collect your stool sample and how blood will be taken. There are no specific lifestyle or dietary restrictions. You may need to modify medications based on the instructions you receive for your colonoscopy.

5 Other relevant information about the research project

Approximately 1500 patients will take part in this study. There will be a group of patients such as yourself with known colonic lesions and also a control group of patients without any known lesions. The research is a collaborative initiative of Westmead Hospital and Clinical Genomics.

6 Do I have to take part in this research project?

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

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.
Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Westmead Hospital or your referring specialist.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. If you do not take part, you will still have the procedure you were scheduled for.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research.

9 What are the possible risks and disadvantages of taking part?

While this research does not involve any interventional treatment, you may be receiving medical treatments that cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms.

These are the possible risks related to the research not the ones related to your standard procedure (you will be advised of those separately):

Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
Bruising and discomfort from blood collection	30% of the time	Usually very mild	Few days
Infection or minor bleeding from blood collection	Less than 5% of the time	May need antibiotics and evaluation in hospital	Few days

10 What will happen to my test samples?

When your colonic lesion is removed it is forwarded to the Anatomical Pathology department at [ ] for evaluation under the microscope. This is part of routine care. It will be stored there for 15 years in line with regulatory requirements.

If you agree to participate in the research your stool and blood samples will be sent to the Clinical Genomics Laboratory for analysis. These samples will be analysed in a de-identified manner, meaning the researchers at the lab do not know your name and cannot identify you. The samples will be stored for 15 years and then physically destroyed in a biohazard environment. We will obtain separate consent to store some of your tissue for a tissue bank.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

13 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include lack of funding or research staff.

15 What happens when the research project ends?

The results of the study will be analysed to determine whether blood and stool tests can predict the degree of dysplasia of colonic polyps. All these results will be published in a well-known medical journal. You will also be sent a letter outlining the results of the study if you wish. You will be followed up as per routine clinical care by the referring doctor or our institution.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project only. Any information obtained in connection with this research project that can identify you will remain confidential. The data collected about you is re-identifiable or coded. Your name and details are in the form of a study code that only the researchers have access to. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. The information is stored in a password protected computer and in a locked cupboard within a secured facility of the endoscopy and Clinical Genomics units.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities, the institution relevant to this Participant Information Sheet or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Information will be presented for the whole group of participants that is analysed (all de-identified). Where an individual case is highlighted, this will also be de-identified.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or NSW privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

18 Who is organising and funding the research?

This research project is being conducted by *Professor Bourke* and associate investigators at Westmead Hospital and Clinical Genomics.

You will not benefit financially from your involvement in this research project even if, for example, your samples or knowledge acquired from analysis of this research prove to be of commercial value to *Westmead Hospital / University of Sydney / Clinical Genomics*.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to *Westmead Hospital / University of Sydney / Clinical Genomics*, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of *Westmead Hospital*.
This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.
If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on *02 9633 5953* or any of the following people:

Clinical contact person

Name	*Dr Farzan Fahrtash Bahin*
Position	*Research Fellow*
Telephone	*02 8890 6700*
Email	*farzan.fahrtash@sydney.edu.au*

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Position	*Hospital Patient Representative*
Telephone	*02 8890 7014*
Email	

You should quote [HREC project number (4079) AU RED HREC/14/WMEAD/322]
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	*WSLHD Human Research Ethics Committee*
HREC Executive Officer	*Ms Kellie Hansen*
Telephone	*02 8890 8183*
Email	*researchoffice@health.nsw.gov.au*

Local HREC Office contact (Single Site -Research Governance Officer)

Name	*Margaret Piper*
Position	*Clinical Governance Officer*
Telephone	*02 8890 9007*
Email	*WSLHD-RGO@health.nsw.gov.au*

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Location	Westmead 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 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 my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Westmead Hospital concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

I understand that, if I decide to discontinue the research project treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

Name of Participant (please print) _____

Signature _____ 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 Study 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 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 - *Adult providing own consent*

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Location	Westmead Hospital

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Westmead Hospital.

Name of Participant (please print) _____

Signature _____ 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 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.