Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*
Westmead Hospital *Hospital Endoscopy Unit*

Title	*A prospective study stratifying patients to follow up intervals based on risk of recurrence post wide field colonic EMR*
Short Title	*The PROSPER study*
Protocol Number	Version 1
Coordinating Principal Investigator/ Principal Investigator	*Professor Michael Bourke*
Associate Investigator(s)	*Dr David Tate, Dr Nicholas Burgess, Dr Eric Lee, Dr Stephen Williams, Dr Lobke Desomer, Dr Halim Awadie, Ms Kathleen Goodrick*
Location	*Westmead Hospital Endoscopy Unit*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, "*A prospective study stratifying patients to follow up intervals based on risk of recurrence post wide field colonic EMR*". This is because your doctor has referred you for removal of a large polyp in your bowel by a procedure called wide field EMR (endoscopic mucosal resection). The research project is aiming to look into how often we need to follow up on the polyp after it has been removed, if it has particularly risky features when we look down the microscope or based on its size.

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?

The study doctor, Professor Michael Bourke, has initiated this research. The purpose is to investigate how often and at what time we perform 'check-up' or surveillance colonoscopies required for people who have had a large polyp removed from their bowel by wide field endoscopic mucosal resection (EMR). Wide field EMR is the procedure by which we remove large and complex polyps from the bowel at Westmead Hospital endoscopy unit. Polyps are growths of the inner lining of the bowel wall that can eventually become cancer if not removed.

After a large polyp is removed at Westmead Hospital it is known that there is roughly a 10-20% chance that a small recurrence of polyp occurs at the site of removal when we perform another colonoscopy to check on things at a later date. We are learning more and more who will have a low risk of recurrent polyp and who will have a higher risk. We know these factors that make recurrence more likely because of studies that have been performed in the past. For example, we know that the larger the polyp (particularly over 4 cm), polyps with particular changes seen under the microscope (called high grade dysplasia) and those who experience bleeding during the initial procedure are at particularly high risk of recurrence. In addition, we have developed a new technique called SCAR to treat the edge of where the polyp was taken from; we have shown this makes the polyp less likely to come back and have shown that it is safe.

We are interested in providing a safe yet streamlined approach for patients undergoing this procedure.

Although we have a lot of experience to support this, we need to prove that this is the case and hence the current study. Understanding this better has benefits for patients; it means our knowledge for individual patients of when they need their colonoscopy repeating will be much improved. There may be no need to take bowel preparation for and undergo a colonoscopy that is not required for that individual person. This may also mean less cost to the patient and the healthcare system.

3 What does participation in this research involve?

Prior to the procedure you will be sent this information sheet together with the information sheets sent to all patients having colonoscopy. On the day of the procedure one of the researchers will discuss the study with you, check that you are suitable for the study and answer any questions you may have. Once all the questions are answered, if you agree to participate, you will provisionally enter the study, on the assumption that a flat polyp of a size 20mm or greater will be found, as expected based on the information we have received from your referring specialist. If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

Everyone referred for removal of a large polyp is eligible to be entered into the study, unless the study doctors feel there are specific reasons why you should not do so.

This study will be conducted over 2-3 years. However, you will only be a participant on 2 occasions, initially at the time when you attend to have your large polyp removed at our centre and next at 6 months (one group), or 18 months (everyone) when we review your polyp with another colonoscopy. The length of time at which you are offered follow up will depend on the particular features of your polyp. This means that your treatment is more individualised than we have been able to offer previously, and may mean that you need less follow up colonoscopies.

If further polyp tissue is present at these repeat examinations an attempt will be made to either remove or destroy remaining polyp at that site. Biopsies from the scar of the previous EMR site will also be taken during the subsequent colonoscopy examinations. We would be grateful if we could keep videos/images of your procedure that will in no way be identifiable as yourself.

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.

Participation in this study will not cost you anything. You will be reimbursed for reasonable travel expenses.

4 What do I have to do?

If you undertake to take part in the project we require no more of your time than in the normal treatment you would receive to undergo a colonoscopy and EMR. Indeed we may need less of your time than if you did not participate as we may find it is safe to skip one of your follow up procedures. As we have made clear above this is because we will have deemed your polyp to be lower risk than normal and therefore believe it is safe to leave follow up for longer.

We would like to contact you two weeks after you have had each colonoscopy to discuss your progress. You do not need to attend the department for more tests or interviews than would normally be required in the course of your EMR procedure.

The only difference between this project and standard care of a patient having EMR is that if you agree to participate we will possibly repeat your procedure less often to check on your polyp and ensure it has not come back (if it is low risk). Therefore while somebody not in the study may have a procedure at 6 months and then 18 months we will check your polyp at 18 months only if it is low risk, or 6 and 18 months if it is high risk.

There will be no restrictions on your lifestyle when undertaking this research project. You will be able to undertake all your normal activities including taking your normal medication.

You will not be able to take part in this study if you are pregnant or have a clotting disorder. If the microscopic analysis (histology) of your polyp indicates high risk features we will not allow you to participate in the study and we will contact you and inform you of this.

5 Other relevant information about the research project

This project involves the named doctors at Westmead Hospital endoscopy unit (experienced colonoscopists and researchers) and patients from all around Australia, who are referred to us by their local specialists.

There will be a large number of patients taking part in the project at the Westmead Hospital site that have large polyps as we have described above. There are eight centres throughout Australia taking part in the study.

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 endoscopy unit.

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 wish to take part you will receive the standard care that we provide to every patient who attends our department. This will include a follow up colonoscopy at 6 months; you will receive SCAR treatment for your polyp. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research, however patients having the procedure in the future will likely benefit due to lower numbers of follow up procedures.

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

The only risk of participating in this study is that if there is recurrence of your polyp and your polyp was thought to be low risk this may be detected later than it would otherwise have been if you did not take part. This may lead to a larger recurrence of the polyp that is more difficult to treat.

Based on our previous patients with low risk lesions who had SCAR technique, recurrence of the polyp is very unlikely (3.9% at 5 months). In addition polyp recurrence that was found was likely to be small and easily treated. That is why we believe this to be a safe approach. Clearly the major advantage of the approach is avoiding the need to attend and undergo bowel preparation for a procedure at 6 months if your polyp is low risk.

It is unlikely that your participation in this research project will uncover a medical condition of which you were unaware. However, if this is the case we will communicate all relevant findings to you and your referring doctor.

10 What will happen to my test samples?

During any EMR procedure the polyp that is removed from the wall of your bowel is sent to the laboratory for analysis under a microscope (histology). The normal procedure for analysis will be followed and the result recorded for this study. There will be no storage of your sample for the specific purposes of this study.

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. This

particularly applies to medicines that thin the blood. 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. Withdrawing from the study will not prejudice your treatment in any way.

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. You should be aware that data collected by ourselves up to the time you withdraw will form part of the research project results. If you do not want us to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

An interim analysis is planned after half the number of patients planned for the study has been recruited. At this point any anomalies will be discussed with the local ethics committee. This is unlikely in this study since we are simply observing how your polyp behaves.

15 What happens when the research project ends?

If you give us your permission by signing the consent document, we plan to discuss/publish the results of the research in coordination with other leading endoscopy units worldwide. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you when they become available, if you wish.

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. Any information obtained in connection with this research project that can identify you will remain confidential.

The information about you will be coded on a research spreadsheet. The data sheets used to record information will be stored in a lockable filing cabinet in a secure room within the Endoscopy unit at completion of the project. The computer spreadsheet file will remain on the Endoscopy Unit

research office computer. This file will be password protected, with the password known only to the investigators. The data stored in the spreadsheet will not be identifiable as yours. A key known only to the researchers will be required to re-identify the information., for example in the case of needing to contact you/

Data will be stored securely for 5 years. Afterwards the paper-based forms will be shredded and put into a confidential waste bin. Electronically stored data will be deleted at this stage. 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.

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 research team accessing health records if they are relevant to your participation in this research project.

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

In accordance with relevant Australian and/or New South Wales privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research 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 *and for the future research described in Section 16* 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 co-ordinated by Professor Michael Bourke and is funded by the Department of Endoscopy at Westmead Hospital.

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 98455555* or any of the following people:

Clinical contact person

Name	Michael Bourke
Position	Director of Endoscopy, Westmead Hospital
Telephone	02 9633 5953
Email	reception@citywestgastro.com.au

Name	Dr David Tate
Position	Advanced Endoscopy Fellow, Westmead Hospital
Telephone	02 8890 9779
Email	ace.westmead@gmail.com

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	Patient Advice and Liaison Service
Telephone	02 8890 7014

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	*Kellie Hansen*
Telephone	*02 8890 8183*
Email	*wslhd-researchoffice@health.nsw.gov.uk*

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

Name	Margaret Piper
Position	Research Governance Officer
Telephone	02 8890 9634
Email	wslhd-rgo@health.nsw.gov.au

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Location	Westmead Hospital *Hospital Endoscopy Unit*

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.

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*

Title	*A prospective study stratifying patients to follow up intervals based on risk of recurrence post wide field colonic EMR*
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Location	Westmead Hospital *Endoscopy Unit*

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 *Hospital Endoscopy Unit*

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.