Health
Western Sydney
Local Health District

NSW GOVERNMENT

Participant Information Sheet/Consent Form

Westmead Hospital Endoscopy Unit

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Title	*Prophylactic endoscopic clip placement to prevent clinically significant post wide field endoscopic mucosal resection bleeding - a randomised controlled trial*
Short Title	*Prophylactic clips to prevent post EMR bleeding*
Protocol Number	*2*
Project Sponsor	
Coordinating Principal Investigator/ Principal Investigator	*Professor Michael Bourke*
Associate Investigators	*Dr Farzan Bahin, Dr Stephen Williams, Dr Eric Lee, Dr Luke Hourigan; A/Prof Gregor Brown, Ms Kathleen Goodrick*
Location	*Westmead Hospital*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have been referred to have a large polyp in your colon removed by endoscopic mucosal resection (EMR). We are researching whether closure of the EMR area at the end of your procedure can reduce the bleeding rates following EMR.
This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments 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 your 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 have the tests and treatments 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 purpose is to investigate whether a simple additional technique applied at the end of the procedure reduces the risk of bleeding following EMR. The technique involves using small metal clips to close the defect (area where the polyp has been removed). We have included how a clip looks like below. The clips are about 2 cm long and provide controlled closure of a defect in any part of the bowel. These clips are already in widespread use during endoscopic procedures. We want to find out if placing these clips routinely can prevent subsequent bleeding. Bleeding rate following EMR is approximately 7% overall and can be as high as 12%. Whilst the bleeding usually settles by itself, it is desirable to reduce the rates of delayed bleeding as much as possible. Therefore we are evaluating whether this new technique can achieve that. In previous studies this approach suggested a reduced rate of delayed bleeding following EMR.

Medications, drugs and devices have to be approved for use by the Australian Federal Government. Endoscopic clips are approved in Australia to treat bleeding following polyp removal, bleeding and perforations in the upper gut and lower intestine. It is not specifically approved for preventative treatment of post EMR bleeding. Hence, preventative clip placement after EMR must be tested to see if it is an effective treatment.

This research has been initiated by the study doctor, Professor Michael Bourke.


Appearance of an endoscopic clip while open

3 What does participation in this research involve?

If you agree to participate in this study, you will be asked to sign the Consent Form. We will check if you meet the criteria to enter this study before and during the colonoscopy. The technique being investigated is used once your polyp has been removed.

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To ensure the groups are similar to start with, a computer allocates each study participant into a group randomly. Neither the doctor nor the study participant can decide which treatment the participant receives. You will be randomised to either receive the additional technique of applying clips to the defect (Group 1) or not receiving the additional technique (Group 2). There is a 50:50 chance of going into the clip group or the non-clip group. 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.

The researchers will also use a small Doppler probe that fits through the endoscope to assess for the presence of blood vessels. This does not involve any risk to you. The Doppler probe simply picks up a blood flow signal – no treatment is performed with the probe.

In addition, the researchers would like to have access to your medical record to obtain information relevant to the study.

You will receive a phone call 14 days following your procedure to see if you have developed any symptoms such as bleeding after your procedure.

The polyp that is being removed from you will be analysed by the pathology department of your hospital and subsequently stored. Tissue samples are routinely stored for 15 years in the anatomical pathology department as per government regulations. This study will be conducted over 5 years *and individual participation* is for approximately 18 months. This time frame is how long we would follow up with you routinely (i.e. even if not participating in the study).

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

There is no reimbursement associated with the research project.

4 What do I have to do?

There is no specific action or restriction required to participate in this study. Prior to your colonoscopy and EMR you will be given specific instructions regarding the EMR technique, bowel preparation, risks and benefits. You will also be given information about medications to avoid, such as blood thinners.

5 Other relevant information about the research project

Nearly 400 patients will participate in this study across four different endoscopy sites in Australia (Westmead, Princess Alexandra, Greenslopes Private and The Alfred Hospitals). Researchers from these sites will combine their results for final analysis. As mentioned, there are two groups that patients will be randomly allocated to: Group 1 (endoscopic clip placement after standard EMR) and Group 2 (standard EMR only)

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 the 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. Other options are available; these include having your EMR procedure carried out as usual (no clips applied pre-emptively). 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 specialist.

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?

Medical treatments often 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 that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
Bleeding	This ranges from 1% to 12% after EMR	May be severe enough to require admission to hospital for observation, blood transfusion and/or repeat colonoscopy. Rarely will need coiling of artery supplying the bowel or surgery	The bleeding may occur up to 1-2 weeks following the procedure. Most of the time the bleeding stops spontaneously. If it persists beyond 12-24 hours the treating will perform an intervention to stop the bleeding.
Endoscopic clip retention	Estimated at 1 in 800	Usually not felt by patients; may interfere with MRI pictures; in rare circumstances the MRI may displace the clips	As the colon tissue grows back, clips fall out by themselves within 30 days. You often don't notice it passing. Clip(s) very rarely stay for a period beyond 30 days (less than 5%)

Please let the study investigators or treating doctors know if you are scheduled to have an MRI following the EMR procedure.

Should a side effect occur this would be addressed either during or after the procedure. The cost of such treatment is fully covered by a public hospital if you are eligible for Medicare.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

10 What will happen to my test samples?

Collection of your tissue is part of routine care and not the purpose of the study. The tissue is analysed and stored as part of routine care.

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 the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing. Withdrawal will not impact adversely on the care you receive or the relationship with your treating team.

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. If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include

- ☐ loss of personnel or location to conduct the study
- ☐ excessive or unexpected adverse effects from the new treatment
- ☐ one treatment is clearly superior to another

15 What happens when the research project ends?

The results of the study will be analysed to determine whether prophylactic clip placement reduces bleeding following EMR 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. 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 hospital computer and in a locked cupboard within a secured facility of the endoscopy unit. No databank of your samples will be established.

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, *Westmead Hospital* 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 *Westmead Hospital* 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. You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. You do not give up any legal rights to compensation by participating in this study.

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. If you have a complaint regarding the treatment you receive or regarding a member of staff, this needs to be directed to the hospital patient representative (details listed below).

18 Who is organising and funding the research?

This research project is being conducted by *Professor Bourke* and associate investigators. The clips used for the study are provided by Cook Medical.

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* .

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to *Westmead Hospital* 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 *Western Sydney Local Health District*.

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 96335053* or any of the following people:

Site Specific Contact Person details -

Clinical contact person

Name	*Dr David Tate*
Position	*Research Fellow*
Telephone	*02 8890 5555*
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

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

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	
Telephone	*02 8890 8183*
Email	*researchoffice@health.nsw.gov.au*

Consent Form - *Adult providing own consent*

Title	*Prophylactic endoscopic clip placement to prevent clinically significant post wide field endoscopic mucosal resection bleeding - a randomised controlled trial*
Short Title	*Prophylactic clips to prevent post EMR bleeding*
Protocol Number	*2*
Project Sponsor	
Coordinating Principal Investigator/ Principal Investigator	*Professor Michael Bourke*
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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 give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the study investigators concerning my disease and treatment relevant to the study for the purposes of this project. I understand that such information will remain confidential.

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 study 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.

I understand that, if I decide to discontinue the study 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.

I consent to the storage and use of blood and tissue samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project
- Other research that is closely related to this research project
- Any future research.

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.

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	*Prophylactic endoscopic clip placement to prevent clinically significant post wide field endoscopic mucosal resection bleeding - a randomised controlled trial*
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Protocol Number	*2*
Project Sponsor	
Coordinating Principal Investigator/ Principal Investigator	*Professor Michael Bourke*
Associate Investigators	*Dr Farzan Bahin,Dr Stephen Williams,Dr Eric Lee, Dr Luke Hourigan; A/Prof Gregor Brown, Ms Kathleen Goodrick*
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 the 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.