

PATIENT INFORMATION AND CONSENT FORM

The Cap-Assisted Resection Margin Assessment (CARMA) technique after polyp resection: a prospective feasibility study of a “novel” approach to reduce polyp recurrence

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Metro South Health

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PARTICIPANT INFORMATION

Title	The Cap-Assisted Resection Margin Assessment (CARMA) technique after polyp resection: a prospective feasibility study of a “novel” approach to reduce polyp recurrence
Short Title	Metro South Health Research Project: The CARMA Technique Study
Sponsor	Metro South Health Study, Education and Research Trust Account (SERTA)
Custodian/Principal Investigator	Dr Alexander Huelsen Katz
Location	Princess Alexandra Hospital

This Participant Information and Consent Form (PICF) is 6 pages long, please make sure you have all of the pages in this document. A signed copy of this form is provided to you, the participant, and another copy is electronically filed in your medical record. The original is retained by the Metro South Health research project.

1 Introduction

You are invited to take part in this study which is assessing a new endoscopic technique that aims to reduce the risk of colonic polyp recurrence after removal during colonoscopy. You are undergoing a colonoscopy as part of your standard medical care which may detect colonic polyps that require removal; we ask that you allow us to trial the CARMA technique if deemed appropriate, following the removal of your polyp by the current standard technique, in order to help us evaluate the effectiveness of this new technique as part of our study.

This Participant Information and Consent Form tells you about the CARMA technique and what is involved in this study. Knowing what is involved will help you decide if you want to take part. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation 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, 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 including donating samples as 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.

You have the right to withdraw your consent to participate at any time. Withdrawing from this study will not affect your relationship with your treating specialist or the hospital.

2 What is the purpose of this study?

The removal of polyps during colonoscopies is an important tool in preventing the development of colon cancers. Unfortunately, polyps can recur after they have been removed, especially if not completely captured at the time of removal, which results in the risk of cancer development. Most commonly, incomplete polyp removal occurs when there is unrecognised leftover polyp at the margins of the polyp removal site.

The CARMA technique is a new method that we have developed which involves the use of magnification and a cap at the end of the colonoscope to further assess the site once the polyp has been removed, in order to ensure there is no polyp remaining and thus allow the resection of any remaining polyp. This study aims to assess whether this technique is effective at improving complete polyp resection rates.

3 What does participation involve?

If you agree to take part you will first be asked to read this Participant Information and Consent form and confirm that you understand what it says. You may discuss the research with your family, friends and local doctor, and you will have the opportunity to ask any questions you may have about this research. When you are satisfied that you fully understand this project, you will be asked to sign this form.

If you participate in this study, you will undergo your colonoscopy which has already been organised for you by your treating physician. If polyps are found during your colonoscopy, they will be removed, as is standard practice during colonoscopies, using standard techniques. One to two polyps will then be chosen to apply the CARMA technique. As mentioned, this involves the use of magnification and a cap at the end of the colonoscope to assess for any left-over polyp that was not completely removed by the standard polyp removal technique. If the CARMA technique finds any left-over polyp, this will then be removed. A tattoo may be placed to mark the polyp location. A further small margin of tissue from the edges of the polyp removal site will also be taken, to allow us to confirm that the polyp was completed after application of the CARMA technique. You will then undergo your follow up with your referring physician as usual. All patients require follow up colonoscopies after polyp removal, as per the national polyp surveillance guidelines; the study team will be involved with your follow up if possible, to assess the polyp removal site where the CARMA technique was applied and see if there has been any recurrence of a polyp there.

You are invited to participate in this project to help us assess the effectiveness of the CARMA technique, because we hope that this new technique may reduce the rate of polyps recurring, and thus reduce the risk of development of bowel cancers.

4 What information is collected from me during the study and how is it used?

Your name, address and contact number will be recorded to allow us to contact you regarding this study but will not be used in any other part of the study. During the study, we will collect and store only relevant demographic information consisting of your age, gender and the reason you are having your colonoscopy. We will also record details from your colonoscopy itself, specifically the characteristics of the polyps assessed, how the polyps were removed and whether there was any left-over polyp found. This information will be collected from your medical record, and all of this information is stored as de-identified data. The polyp specimens go directly to the pathology lab, as is the case with any standard colonoscopy, and are analysed by the pathologists in the lab and stored as per the usual protocol of the lab. The researchers involved in the study do not keep any of your specimens, and will only receive the lab analysis results from the polyp specimens. If you return for a follow up colonoscopy, we will only record whether any left over polyp was seen during the colonoscopy or confirmed with any specimens sent to the lab. Other than these details listed, no other information is collected as part of the study.

5 What are the possible benefits of taking part?

We hope that the CARMA technique will improve our ability to detect leftover polyps at the time of removal, so if we apply this technique for any polyps removed during your procedure, you may have a lower risk of polyp recurrence.

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

Your participation in this study and the use of the CARMA technique during your colonoscopy does not increase your risk of any complications.

A standard colonoscopy does have a risk of the following anaesthetic or procedural complications:

- Mild pain or discomfort
- Nausea and vomiting
- Faintness or dizziness
- Headache
- Pain, redness or bruising at the sedation injection site
- Muscle aches or pain
- Allergic reaction to medications given during the procedure, including severe allergic reactions such as anaphylaxis
- 1 in 1,000 risk of a hole accidentally being made in the bowel (perforation), which rarely requires bowel surgery to repair
- 1 in 100 risk of significant bleeding, which rarely may require further endoscopy, blood transfusions or surgery
- Missed polyps, growths or bowel disease

- Heart or lung problems, such as heart attack or pneumonia
- Nerve injuries, which are usually temporary
- Worsening of a pre-existing medical condition
- Severe infection
- Stroke resulting in brain damage
- Death.

The use of the CARMA technique does not increase the risk of any of these complications or any other complications. The CARMA technique does take an additional 1-2 minutes to apply to each polyp; as such, the use of the CARMA technique on a maximum of 1-2 polyps during your procedure may lengthen your procedure and anaesthetic time by a maximum of 4 minutes.

7 Will I find out the results of the research using my tissue?

You will receive the results of your colonoscopy from your doctor, but the results of research done as part of this study will not be notified. This is because results may not be available for a long time and are highly unlikely to be of relevance to you as an individual patient. Research results are usually not linked back to the individual patient they have come from. Research can take a long time to complete and must use results from many people before results are analysed.

You have the legal right to access your medical records at any time. In the course of your medical care you will receive the results of your procedure from your doctor. This information is a part of your permanent medical record, but you will not receive specific research results. This is because research by its very nature, is experimental, can take many years, and uses data from a large number of people, so what a researcher discovers in this context may be of little value to you or your future health.

8 How is my privacy protected?

Your privacy is respected. The research project will take careful steps to ensure that personal information about you is kept private and confidential. Your name, address, phone number, Medicare number and any other identifying information will not be associated with your results. Additional clinical information as described above will be supplied as needed, but personal identification will not. No one outside the research process (e.g. third parties), other than as required by law – acceded to only under court order, will have access to results from any individual, which also protects your privacy.

By signing the consent form you consent to the study doctor and relevant research staff collecting and using information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. 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. Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and Queensland privacy and other relevant laws, you have the right to request access to your information collected and stored by the study 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.

It is anticipated that the results of this research project may 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.

9 Are there any financial implications for me?

The success of this research depends on your goodwill. There is no financial payment to you for participating in this research. There is no cost to you for participating in a Metro South Health research project either.

10 Does the decision to participate affect my care in any way?

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 Hospital. Your care will not be affected by your decision in any way.

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

Participation in any research study 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 study at any stage. No matter what you decide to do, it will not affect your care now or in the future. You are under no obligation to participate. 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.

12 Who has reviewed this 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 Metro South Health.

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.

13 What if I change my mind later?

If you decide now that you would like to participate in this study, but change your mind at any later time, just contact your treating doctor who will let us know that you do not want us to use your tissue or alternatively you may contact the Research Project Manager, Dr Alexander Huelsen Katz, directly on 07 3176 1613 (during office hours) or 07 3176 2111.

14 What if I have more questions?

The person you may need to contact will depend on the nature of your query. If you have any questions, please talk to your doctor or nurse, or the Metro South Health Human Research Ethics Committee (HREC) on (07) 3443 8049 or make contact with the Research Project Manager, Dr Alexander Huelsen Katz, on 07 3176 1613 (during office hours) or 07 3176 2111.

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:

The reviewing HREC approving this research:

Reviewing HREC name: Metro South Health Human Research Ethics Committee

Position: HREC Coordinator

Telephone: (07) 3443 8049

Email: MSH-Ethics@health.qld.gov.au

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CONSENT FORM

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Location	Princess Alexandra Hospital

Consent - read this section carefully and indicate at the end whether you consent.

Statement of Informed Consent

1. You will receive a signed copy of the Participant Information and Consent Form (the original will be retained by the research project and a copy placed in your medical record).
2. The use of the CARMA technique during your colonoscopy and subsequent research in this Metro South Health research project will be conducted in accordance with the ethical and scientific principles set out by the National Health and Medical Research Council of Australia.
3. There will be no additional charges if you choose to participate, nor any financial benefit.
4. Participation is completely voluntary. You may withdraw from participating in the Metro South Health research project at any time without affecting your medical management, and (if requested) any recorded information will be removed from the study database. Choosing not to take part in the establishment of the research project will not affect your medical treatment in any way.
5. Medical information pertaining to your sample will be released in confidence with the strict provision that these records will be used only in connection with the research being carried out. You will not be identified as an individual in any reports or subsequent publications resulting from the research.
6. Personal information that you provide as part of your treatment will be treated confidentially, and will only be identifiable by an ID code. This information therefore will not carry your name and the only people with access to personal information will be the personnel responsible for the database and the persons responsible for the Metro South Health research project.

Declaration by Participant

I have read or had read to me in a language that I understand the Participant Information sheet and this document and I understand the purposes, procedures and risks of this research project as described within it. I have been given a copy of the Participant Information sheet to keep.

I understand the purposes, procedures and risks of the CARMA technique study described in this document.

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

I understand that my participation in the CARMA technique study is voluntary and I am free to withdraw my consent at any time and this will not affect my clinical management.

I acknowledge that my involvement may not be of benefit to me.

I freely agree to participate in this research project as described.

Name of Participant

Date

Signature of Participant

Please note a guardian (over 18 years of age) is required if patient is willing to consent but unable to sign. A witness signature is only required if a subject is unable to read or if a legally acceptable representative is unable to read. In this case an impartial witness should be present during the entire informed consent discussion. The 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 Guardian/
Witness**

**Relationship to
Participant**

Date

**Signature of
Guardian/Witness****Declaration by Researcher/Principal Investigator/Designated Officer**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation. I have explained the nature and purpose of the Metro South Health research project to the above participant and have answered their questions.

**Name of Researcher/Principal
Investigator/Designated Officer**

Date

**Signature of Researcher/Principal
Investigator/Designated Officer****If an Interpreter was used, please fill in the following**

I have interpreted the Participant Information and Consent Form to the above in a language he/she may understand.

Language:**Relationship to participant:****Interpreter's Name (print):****Signature:****Date:**

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

Metro South Health

FORM FOR WITHDRAWAL OF PARTICIPATION

Title	The Cap-Assisted Resection Margin Assessment (CARMA) technique after polyp resection: a prospective feasibility study of a “novel” approach to reduce polyp recurrence
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Location	Princess Alexandra 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 Princess Alexandra Hospital.

Name of Participant

Date

Signature of Participant

Declaration by Researcher/Principal Investigator/Designated Officer

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 Researcher/Principal Investigator/Designated Officer

Date

Signature of Researcher/Principal Investigator/Designated Officer

If an Interpreter was used, please fill in the following

I have interpreted the Form for Withdrawal of Participation to the above participant in a language he/she may understand.

Language:	Relationship to participant:	
Interpreter’s Name (print):	Signature:	Date:

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