Title of research study: **Use of a Distal Colonoscope Attachment to Increase Detection of Sessile Serrated Adenomas**

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Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are about to undergo a screening colonoscopy at UC Davis Medical Center.

What should I know about a research study?

(Experimental Subject's Bill of Rights)

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any drug or device to be used.
  - Any common or important discomforts and risks.
  - Any benefits you might expect.
  - Other procedures, drugs, or devices that might be helpful, and their risks and benefits compared to this study.
  - Medical treatment, if any, that is available for complications.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document**.**

Who can I talk to?

The person in charge of this study is Dr. Joseph Marsano. If you have questions, concerns, or complaints, or think the research has hurt you, please contact the Lead Researcher at 916-734-8696.

For non-emergency issues, you can call the UCDMC Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to Gastroenterology fellow on call. In the case of an emergency, dial 911 from any phone.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). Information to help you understand research is on-line at http://www.research.ucdavis.edu/policiescompliance/irb-admin/.You may talk to a IRB staff member at (916) 703-9151, hs-irbadmin@ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.

- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

The overall goal of this research is to determine if adding an extra accessory device to the tip of the colonoscopy camera will affect the performance of the colonoscopy and increase detection of colon polyps.

We are studying one particular attachment device, which is already approved for use during colonoscopy.

In routine clinical practice, screening colonoscopies are done without attachment devices (an attachment to the end of the colonoscope to aid in seeing polyps). The device we are examining is called the Endocuff Vision, which is a disposable device with soft hair-like projections that aids in polyp detection during colonoscope withdrawal. This device is already approved for use during colonoscopy and are typically used at the discretion of the endoscopist to increase detection of polyps. We are investigating whether the use of this device increases the detection of a specific pre-cancerous polyp sub-type called a sessile serrated adenoma. Currently, the gastroenterologists that are participating in this study have experience using this device in screening colonoscopies. Previous studies have suggested that the use of this device may increase the detection of sessile serrated adenomas; however, no studies to date have focused solely on sessile serrated adenomas as the primary outcome. The goal of our study is to answer this question:

(i) Is there a difference between colonoscopy with Endocuff Vision and colonoscopy without Endocuff Vision in detection of sessile serrated adenomas?

How long will the research last?

We expect that you will be in this research study for the completion of your colonoscopy.

How many people will be studied?

We expect about 1374 people will be in this research study.

What happens if I say yes, I want to be in this research?

If you say yes to this study, we will assign you randomly into one of two groups. One group will have a device attached to the end of their colonoscope, and the second group represents the typical colonoscopy group (no special attachment device will be used).

We will proceed with your procedure as scheduled.

This is a one-time study. You will not be contacted after this for any information. Once we collect the information that we need, we will remove any links or connections such as your name, so that the information cannot be tracked back to you.

If you are assigned into the group with a device attached, the additional device will be provided at no additional cost to you or your insurance.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

If you decide to not participate, your scheduled colonoscopy will proceed as scheduled. Not participating will not affect your procedure or medical care in any way.

The treatment you get will be chosen by chance, like flipping a coin. You will have a one in two chances of being given the treatment. You will not be told which treatment you are getting; however, your study doctor will know.

What are my responsibilities if I take part in this research?

If you take part in this research, you will not be given any additional responsibilities. However, as standard practice, you should keep the research team updated regarding any adverse events that occur to you after your procedure.

What happens if I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you. You will still receive standard treatment of a colonoscopy with no device attachment.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you.

Is there any way being in this study could be bad for me?

Apart from the standard risk of undergoing a colonoscopy, there are no additional risks anticipated from being a part of our study.

You will be assigned to a study group at random (by chance). Your assignment is based on chance (like a coin flip) rather than a medical decision made by the researchers. The study group you are assigned to might not be the group you would prefer to be in. It might also prove to be less effective or have more side effects than the other study group, or standard treatments available for your condition.

There may also be risks to your privacy. The Researchers will store study records and other information about you in a secure location and will grant access only to those with a need to know. However, just like with other personal information kept by your health care providers, your banks, and others, even these safeguards cannot guarantee absolute protection of the data. If private information gets into the wrong hands, it can cause harm. Although rare, there are reported cases of breaches that have resulted in discrimination in insurance or employment.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include increase detection of all colon polyp subtypes.

What happens to the information collected for the research?

Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB, the

Food and Drug Administration (FDA), and other University of California representatives responsible for the management or oversight of this study.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

During your participation in this research, data will be collected about you. The de-identified data taken from you for this study, will become the property of the University of California. The data obtained in this research, may be used in other research, and may be shared with other organizations but this will be de-identified information and cannot be traced back to you. The information could lead to discoveries or inventions that may be of value to the University of California or to other organizations. Under state law you do not have any right to money or other compensation stemming from products that may be developed from the specimens.

If you agree to participate in this research study, a signed copy of this consent document will be filed in your electronic medical record (EMR), the clinicaltrials.gov statement, and the sponsors, monitors, auditors, the IRB, the Food and Drug Administration (FDA will be granted direct access to your research records to conduct and oversee the study. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

If we access protected health information (e.g., your medical record), you will be asked to sign a separate form to give your permission. Your medical records may become part of the research record. If that happens, your research records may be looked at by the sponsor of this study and government agencies or other groups associated with the study. They may not copy or take your personal health information from your medical records unless permitted or required by law.

Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/legal/privacy/) and in an attached document.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include poor colon prep, inability to complete your procedure with the standard colonoscope equipment, leading the endoscopist to switch to a different equipment.

What else do I need to know?

As the endocuff accessory device has been approved for use as part of standard practice, any additional cost will not be the responsibility of the study. The endocuff is an additional tool to detect polyps at the discretion of the endoscopist. There is no additional billing when this device is used, and it is included in your standard screening colonoscopy visit. Therefore, there is no expectation that you will incur additional costs if you are randomized to colonoscopy with endocuff. You or your health plan will be billed for the costs of routine medical care you receive during the study. These costs may include operating room fees, pharmacy charges, treatments, hospitalization, scans, etc. You will be expected to pay for the usual deductibles and co-payments, and for any routine care that is not covered.

For more information about possible costs, please contact the research team. The research team can follow UC Davis Uninsured Non-Emergency Estimate Policy (Policy ID 1883) to work with their department and Decision Support Services to get you a cost estimate.

It is important that you promptly tell the person in charge of the research if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, you may call the IRB Administration at (916) 703-9151 or email at HS-IRBAdmin@ucdavis.edu.

You will not be compensated for taking part in this study.

Do not write below this line. For IRB stamp and version date only.

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
1164295	February 26, 2019

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	

Do not write below this line. For IRB stamp and version date only.

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