Informed Consent for Outcomes of Sessile Polypectomy Using the "Grasp and Snare" Technique through a Double-Channel Scope in a Community Setting.

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

TITLE: "Informed Consent for Outcomes of Sessile Polypectomy Using the Grasp and Snare Technique through a Double- Channel Scope in a Community Setting"

PROTOCOL NO:	#DGLJAD: SSA1
SPONSOR:	**Investigator Initiated Study**
INVESTIGATORS:	**Daniel G. Luba, M.D./James A. DiSario, M.D.** **23 Upper Ragsdale Drive** **Monterey, California 93940**
SITE(S):	Community Hospital of Monterey Peninsula OPSC 23625 Holman Highway P.O. Box HH Monterey, CA 93942 Monterey Bay GI Consultants, Inc. Monterey Bay Endoscopy Center, Inc. Monterey Bay GI Research Institute, Inc. 23 Upper Ragsdale Drive Monterey, CA 93940
STUDY-RELATED NAMES:	Daniel G. Luba, M.D.; James A. DiSario, MD Maydeen Ogara, AS, CCRP, AGTS
PHONE NUMBER(S):	#831-657-3170

Community Hospital of the Monterey Peninsula
INSTITUTIONAL REVIEW BOARD
Approval date: 8/6/13 Exp: 8/5/14
Initial: KL

Pt. Initials_____

This consent form may contain words that you do not understand. Please ask the study doctor or the clinical research study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about your participation in the study or to discuss with family or friends before making your decision.

Why is this study being done?

This study is being done to determine the outcome for patients who have large (1.2 cm or greater) flat, right-sided colon polyps removed by physicians at the Community Hospital of the Monterey Peninsula (CHOMP) and the Monterey Bay Endoscopy Center (MBEC). You have been advised by your doctor to have a colonoscopy procedure for screening, surveillance or for other indications with the possible removal of polyps found during your examination. A colonoscopy is a visual examination of the inside of your colon. Most colonoscopies are performed using a colonoscope with a single channel that allows the passage of instruments used to remove polyps and obtain biopsies. Most large polyps are removed with a snare, which is a small lasso that is placed around the polyp. The snare is then closed and an electric current is applied to remove the polyp. This technique is very effective for mushroom shaped polyps (polyps with a stalk or stem). However, a new type of flat polyp that has been recently described, which may be a precursor to colon cancers that occur on the right side in the colon. These flat polyps can be very challenging to remove using standard methods. Your doctors have employed a technique to remove these polyps for the last several years. A dual-channeled colonoscope (with 2 channels) is utilized in most procedures, and if a large, flat polyp is found, the polyp is lifted from the surface of the colon by injecting saline into the base of the polyp to lift it from the surface of the colon tissue. A biopsy forceps is then passed through one of the channels and a snare is passed through the other channel. The biopsy forceps is then passed through the open lasso-shaped snare. The polyp is grasped with the biopsy forceps and then the snare is passed over

the polyp. By using both instruments, the polyp can be more easily removed. The purpose of this study is see how often large, flat polyps are encountered in a community setting and how effective this procedure is in their removal. This study may help us to better understand the benefits and risks of this procedure. The outcomes that we will study include length of the procedure, success of the procedure, how well the polyp removal method works, if the method helped with your medical care, and any complications following the procedure.

What will happen in this study?

Initial Study Encounter

You will be interviewed by your study doctor or the clinical research manager to see if you are eligible and willing to take part in the study.

Colonoscopy and Polyp Removal of Large, Flat, Right-sided Polyps

You have been advised by your doctor to have a procedure called endoscopic colonoscopy with the possibility of the removal of large, flat colon polyps. This involves passing an endoscope (flexible lighted tube) through your colon to examine the area for possible polyp growth. If a colon polyp greater than or equal in size to 1.2cm is found, it will be removed with a special technique using a double-channel endoscope with a biopsy in snare removal method. The doctor can then send the removed polyp tissue to pathology for further examination and possibly a better understanding of patient diagnosis and what the patient's treatment plan should be.

Additionally, the biopsy specimens will be sent to the University of Utah Health Sciences Center for further analysis as part of this research. The specimens that are sent to the University for evaluation will be de-identified (or anonymous) and will be used for other genetic research.

Your procedure is not experimental. It is recommended by your doctor and will be done according to the usual standards of good medical care. This research is only to record the results of your treatment. There is no risk to you above what is normally associated with your procedure. The study includes review of medical records and analysis of de-identified data for people who have already had the procedure performed and those patients will be included with patients who will be prospectively enrolled once the study is approved to create the population basis for the study.

There is no financial support for this project and your insurance and/or you will be billed for treatment in the usual manner.

The choice to participate in this information gathering research is completely voluntary. You may choose not to submit your images and/or biopsy specimens and this choice does not preclude you from receiving your necessary medical care. If, at any point you decide you no longer wish to participate in the study, notify the research personnel so that your information can be removed from our database for any future analysis. From the time you decide you no longer wish to participate, no new information will be collected. However, any information gathered prior to this will still be utilized for the purposes of this research.

☑ I understand that by checking this box, I specifically consent to the storage and use by other researchers of my information and specimens obtained during the course of this study as part of this research. This consent shall remain even if and after I withdraw from the Study and/or revoke the Authorization for Use and Disclosure of Health Information

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Follow-up

Your doctor or research staff will ask you how you are doing at 30 days and possibly again at 1 year after your procedure(s).

How long will I be in this study?

You will be part of this study until completion, or until the time you decide to withdraw from the study. You will only be consented for this project one time, and that consent will cover all of the data collection for colonoscopy with possible polypectomy procedures performed as part of this study.

What are the risks of this study?

All procedures are being done only for your medical care by your doctor who is trained and experienced. There is no risk to you beyond what is associated with the procedure that you require for your medical care. However, with regard to this study, which is observational in nature, there is a very small risk of disclosure of your personal medical information. The chance of this happening will be minimized by keeping all records in secure computers with password protection and in locked file cabinets.

Are there benefits to taking part in this study?

There may be no personal benefits for you to participate in this study. It is also possible that you will have more careful follow-up and a higher likelihood of disease diagnosis and therapy due to participation in the study, yet this is not guaranteed. Your participation may help other patients in the future as physicians learn from these study results.

Will I need to pay for the tests and procedures?

All procedures will be billed to you or your insurance company in the usual fashion. The procedure is being done in the standard way for your medical condition and is not experimental. However, you will not be billed for any study-related costs, such as collecting and recording information from your treatment.

What other choices do I have if I don't take part in this study?

This is not a treatment study, only a review of the medical information related to your procedure. You do not have to participate in this study to receive the treatment for your condition. This study simply provides a way for your study doctor to follow the results of this procedure. Your procedure will be performed in exactly the same way whether or not you participate in this study. Your medical treatment is not on the condition of obtained consent for this study, nor on your signature on this document.

What happens if I am injured because I took part in this study?

There are no physical risks associated with participation in this study which only involves the collection of information. The only possible risk is unintentional disclosure of medical information that identifies you.

Who will provide the source of funding?

No funding will be used to conduct this project.

What are my rights if I take part in this study?

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. You have the right to refuse to sign this authorization without penalty or loss of benefits.

The study doctor may stop you from taking part in this study at any time if you do not consent to changes that may be made in the study plan. If you decide to withdraw from the study, you will still receive necessary medical care for your condition and you will not lose medical care benefits to which you are entitled.

What if there are new findings?

You will be told of important new findings or any changes in the study or procedures that could change your decision to be in the study. You may be asked to sign a revised consent form if this occurs.

Who can answer my questions?

You may talk to your study doctor or the study coordinator at any time about any questions or concerns you have on this study.

Contact: Daniel G. Luba, M.D., James A. DiSario, M.D. or Maydeen Ogara at #1-831-375-3577 for any of the following reasons:

- if you have any questions about your participation in this study,
- if at any time you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the study

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Community Hospital of the Monterey Penninsula Institutional Review Board (CHOMP IRB)

40 Ryan Court, Suite 220

Monterey, California 93940

#1-831-658-3649

Do not sign this consent form unless you have had a chance to ask and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What information may be used and given to others?

If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about physical exams, laboratory, x-ray, and other test results
- Records about the study device

Who may use and give out information about you?

Information about your health will be used only by the study doctors and staff.

Who might get this information?

Your information will be kept in an identified fashion, for study staff only, and a de-identified fashion for analysis and future publications. Your information will be kept in password protected computer programs and any paper information will be kept in a secure locked filing system at the Monterey Bay GI Research Institute and will only be accessed by study doctors and study staff working on this project. No protected health information will be disclosed to any parties other than governmental agencies listed below as required by law. It is possible that these governmental agencies could make additional disclosures which will not be covered under the Health Information Portability and Accountability Act (HIPAA)

In addition, confidential information about you and your health, which might identify you, may be given to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Office of Human Research Protections or other domestic or foreign governmental bodies, if required by law and/or necessary for oversight purposes
- Community Hospital of the Monterey Peninsula's Institutional Review Board

Why will this information be used and/or given to others?

Information about your health and the results of this research may be published in scientific journals or presented at medical meetings. However, in these situations your identity will not be disclosed.

The information may be reviewed by CHOMP IRB- a group of people who perform independent review of research as required by regulations.

What if I decide not to give permission to use and give out my health information?

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be involved in this research.

May I review or copy the information obtained from me or created about me?

You have the right to review and copy your health information from your health care providers and hospitals. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information from the study records until after the research is completed.

May I withdraw or revoke (cancel) my permission?

Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after the date of receipt of withdrawal notification. Information that has already been gathered can and/or will be used. Access to study-specific protected health information will be reinstated upon completion of the research.

Is my health information protected after it has been given to others?

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission. However, these are the same doctors who are providing your medical care.

Consent

I have read the information in this consent form (or it has been read to me). All my questions about the study and my participation in it have been answered. I agree to take part in this study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent form for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____ _____

(Date/Time) (Printed Name of Subject) (Subject Number)

_____

(Signature of Subject)

_____ _____

(Date/Time) (Printed Name of Person Conducting Informed Consent Discussion)

_____

(Signature of Person Conducting Informed Consent Discussion)

---------- Use the following only if applicable ----------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

(Date/Time)	**(Printed Name of Witness)**

(Signature of Witness)

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak and read English.

CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in an experimental procedure. Before you decide whether you want to participate in the experimental process, you have the right to:

1. Be informed of the nature and purpose of the experiment;
2. Be given any explanation of the procedure to be followed in the medical experiment, and any drug or device to be utilized;
3. Be given a description of any discomforts and risks reasonably to be expected from your participation in the experiment;
4. Be given an explanation of any benefits reasonably expected from your participation in the experiment;
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to you and their relative risks and benefits;
6. Be informed of the avenues of medical treatment, if any, available to you after the experimental procedure if complications arise;
7. Be given an opportunity to ask any questions concerning the medical experiment or the procedures involved;
8. Be instructed that consent to participate in experimental procedure may be withdrawn at anytime and that you may discontinue participation in the medical experiment without prejudice;
9. Be given a copy of this form and the signed and dated written consent form; and
10. Be given the opportunity to decide to consent or not to consent to the medical experiment without the intervention of any element of force, fraud, deceit, coercion, or undue influence on the subject's decision.

I have carefully read the information contained above and I understand fully my rights as a potential subject in a medical experiment involving people as subjects.

Signature (patient) Date

Signature (parent/legal guardian/conservator) Date

If signed by other than patient, indicate relationship

Witness Date

A COPY OF THIS FORM MUST BE GIVEN TO THE PATIENT. THE ORIGINAL MUST BE PLACED IN THE MEDICAL RECORD.

CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in an experimental procedure. Before you decide whether you want to participate in the experimental process, you have the right to:

1. Be informed of the nature and purpose of the experiment;
2. Be given any explanation of the procedure to be followed in the medical experiment, and any drug or device to be utilized;
3. Be given a description of any discomforts and risks reasonably to be expected from your participation in the experiment;
4. Be given an explanation of any benefits reasonably expected from your participation in the experiment;
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to you and their relative risks and benefits;
6. Be informed of the avenues of medical treatment, if any, available to you after the experimental procedure if complications arise;
7. Be given an opportunity to ask any questions concerning the medical experiment or the procedures involved;
8. Be instructed that consent to participate in experimental procedure may be withdrawn at anytime and that you may discontinue participation in the medical experiment without prejudice;
9. Be given a copy of this form and the signed and dated written consent form; and
10. Be given the opportunity to decide to consent or not to consent to the medical experiment without the intervention of any element of force, fraud, deceit, coercion, or undue influence on the subject's decision.

I have carefully read the information contained above and I understand fully my rights as a potential subject in a medical experiment involving people as subjects.

_____

Signature (patient) Date

_____

Signature (parent/legal guardian/conservator) Date

_____

If signed by other than patient, indicate relationship

_____

Witness Date

A COPY OF THIS FORM MUST BE GIVEN TO THE PATIENT. THE ORIGINAL MUST BE PLACED IN THE MEDICAL RECORD.

Experimental Subject's Bill of Rights

Required for California Sites Only

The Protection of Human Subjects in Medical Experimentation Act (California Health and Safety Code 24170 – 24179.5) requires that a potential experimental subject (or subject's conservator, guardian, or other representative) be provided with a list of the rights of a subject in a medical experiment. A copy of this Experimental Subject's Bill of Rights should be provided to a subject prior to consenting to participate in any medical experiment.

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or other procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of a signed and dated written consent form as provided for by California law.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

_____

Signature of Subject (Conservator, Guardian, or Other Representative)

_____

Date