Participant Name: _____ **Date:** _____

Study Title: Prospective RCT Of Water Exchange (WE) vs. WE Plus Cap-Assisted Colonoscopy

Principal Investigator: **Felix W. Leung, MD,** **Phone: 818-891-7711, X32520**

Co-Investigator: James Sul, MD; Noam Jacob, MD

INTRODUCTION

You are being invited to take part in a research study at the VA Greater Los Angeles Healthcare System under the direction of Dr. Felix Leung and his research team. Before you decide to take part, it is important for you to know why the research is being done and what it will involve.

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

Your participation in this study is voluntary. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient. If you decide to take part, you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled.

BACKGROUND AND PURPOSE

You are asked to participate in this study because as part of your standard of care, you have already been scheduled and have received instructions on the standard preparation for your unsedated colonoscopy. The colonoscopy procedure described in this document is standard of care and is not a research procedure.

The purpose of this study is to compare the pain in two different, but normally, used methods of colonoscopy in patients examined by the water exchange method alone versus water exchange plus the cap. This study involves the use of an FDA approved, commercially available and clinically used, transparent cap that will be fitted onto the end of the colonoscope at the tip. The aim of this study is to determine which method (with or without cap) is more effective in diminishing pain during the insertion of the colonoscope.

There are two arms or groups to this study: One control group and one group which will use water plus a cap instead of air.

- Control Method (WE): This group will have the air in the colon removed and replaced with water to guide the insertion of the colonoscope.
- Study Method (WECAP) This group will use water instead of air plus the transparent cap fitted onto the end of the colonoscope.

INVESTIGATOR DISCLOSURE

The VA Clinical Merit Review Board is providing financial support and/or material for this study.

DURATION OF THE RESEARCH:

This is a multi-site study designed to enroll 256 participants in total. We anticipate enrolling up to 150 patients from the VA Greater Los Angeles Healthcare System. The performance site at the WLAVA will be in building 500, 5 East Clinical Procedure Center. The other study sites include: Sacramento VAMC; Palo Alto/Livermore VAMC.

This study is expected to take up to 5 years to complete. The expected duration of your participation in this study is 1 hour for the colonoscopy procedure.

STUDY PROCEDURES

You will be asked to read and sign this consent form before taking part in this study. There are no experimental procedures in this study. There may be reasons why you may not be eligible to take part in the study. This will be discussed with you by the study staff. You must inform the study staff of all past and present diseases and allergies of which you are aware, all medications and drugs that you are currently taking.

As part of your standard care, you have already been scheduled and have received instructions for the standard preparation of your unsedated colonoscopy. If you do not meet eligibility criteria, you will be offered usual unsedated colonoscopy using standard method, outside of the research study. If you are eligible, and have signed the consent form, you will undergo the following assessments: a series of questionnaires, physical examination, and unsedated colonoscopy with the standard (control) or study methods.

If you decide to take part in this study, this is what will happen:

You will be randomly assigned (by chance which is similar to flipping a coin) to one of the two groups, control method or the study method. What follows is a description of the procedures for research purposes.

You will prepare yourself for the examination in the standard fashion (as you have already been instructed) one day before your colonoscopy. When you report for the examination, you will be asked to complete a series of questionnaires related to your expectation of the examination before the actual colonoscopy procedure. You may skip any questions that you don't wish to complete.

During the screening visit, you will undergo the following:

- The study staff will interview you and review your record to obtain information about your social security number, address, telephone number, age, gender, and use of pain medications (Demographic Questionnaire).
- The control and study methods will be explained to you.
- You will be asked to agree to allow the doctor to perform your colonoscopy by either the control or study method based on a code inside an envelope which the doctor will pull from a box immediately before the start of your examination, customarily scheduled after your screening visit.
- During the colonoscopy procedure, your vital signs and other procedural data (e.g., pain scores) will be monitored and recorded, in the usual manner.
- After the examination, you will be asked to complete two (2) questionnaires asking you to report on your experience of any abdominal discomfort, and your satisfaction and with the colonoscopy (Patient Satisfaction and Patient Willingness to Repeat).

Tell the investigator or research staff if you change your mind about staying in the study.

FOLLOW-UP

As a follow-up to your colonoscopy procedure, the Study Coordinator will call you at three (3) different times to inquire about your well-being by asking you to answer yes or no to a list of side effects or symptoms. The Study Coordinator will call you at 24 hours after your colonoscopy procedure, then again at 7 days and at 30 days after the procedure. Each time, the Study Coordinator will ask you the same set of questions.

POSSIBLE RISKS OR DISCOMFORTS

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some or none of the risks or side effects listed. Rare, unknown, or unforeseeable (unexpected) risks also may occur.

General Risks: Risks common to all forms of colonoscopy (sedated or unsedated, irrespective of the clinical study) include: pain, bloating, medication reaction, bleeding, perforation, intravenous site reaction and rarely death. Risk from discomfort of putting water in the colon is rare. Water method and cap-assisted method have no more known side effects than conventional method of colonoscopy.

In case your procedure is stopped due to pain or other findings, then you may need to undergo a second bowel preparation and a repeat colonoscopy with sedation.

Discomforts and Inconveniences: You may be inconvenienced and feel uncomfortable about answering some of the questions about the colonoscopy procedure and preparation, your abdominal discomfort and/or satisfaction associated with the examination.

The risks involved in the colonoscopy procedure are not part of this research, but part of standard of care. There may be risks or discomforts in this study that are currently unforeseeable or unknown.

POTENTIAL BENEFITS

There are no direct benefits to you from your taking part in this research study. However, the information we get from this study might help us treat future patients as a result of knowledge gained from the research.

ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH

You may choose not to participate in this study. If this is your decision, you will be offered usual unsedated colonoscopy using standard method, outside of the research study.

You may discuss these options with your doctor.

CONFIDENTIALITY

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- Information that is collected during the study will be stored at the research site. Paper copies will be kept in locked files and computer files will be protected by passwords.
- Your information will also be disclosed to others as explained in this consent form. Your information will be combined with information from other people taking part in the study.
- Information about you will be combined with information from other people taking part in the study.
- We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.

We will not share your records or identify you unless we are legally required. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Greater Los Angeles IRB, our local Research and Development Committee. Research records about you may be reviewed by the sponsor for study purposes. Copies of research records about you may be given to the sponsor but they will not contain any identifiers.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

COSTS TO PARTICIPANTS AND PAYMENT

You will not be charged for any treatments or procedures that are part of this research study. The colonoscopy procedure is part of standard of care, and you will still need to pay the insurance required co-pay for this procedure if you usually pay co-payments for VA care and medications.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. **However, no additional compensation is available.**

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

Dr. Felix Leung at 818-891-7711, X32520 or you may call the hospital operator and ask to have Dr. Leung paged at X3074, **or Dr. James Sul at 310-709-5746, or Dr. Noam Jacob at 310-869-0927.**

AFTER HOURS: Dr. Felix Leung at 818-284-3327.

Emergency and ongoing medical treatment will be provided as needed.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

In the event of a research related injury or if you experience an adverse reaction, please immediately contact your study doctor at (818) 891-7711, ext 32520 during the day and (310) 268-3596 after business hours. If you need emergency hospitalization in a private hospital because you are unable to come to the VA, have a family member or friend contact your study doctor so that the VA can coordinate care with the private hospital.

YOUR RIGHT TO TERMINATE PARTICIPATION

It is up to you to decide whether or not to take part in this study. You may choose not to participate in this study. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may choose to continue standard care for your condition.

Your participation in this research is voluntary. You have the right to leave the study at any time. If you choose to stop participating, that will not affect your relationship with the VA or the care that you may receive here. There are no known consequences of withdrawal from this study. If you do not finish the full number of study visits, for safety reasons you will return for a discontinuation visit that will include a physical examination and review of diary data. You will also be asked questions to see if you have had any new symptoms or side effects.

You will be referred to your VA or community health care provider for continuing treatment. If you do not have a health care provider, you will be referred to one in the community, or if you qualify, to a VA health care provider.

RIGHT OF INVESTIGATOR TO TERMINATE YOUR PARTICIPATION

The investigator, Felix Leung, M.D., has the right to end your participation in this study for any of the following reasons: If you do not or are unable to follow the study plan such as failure to keep appointments, if you need treatment other than that allowed by the study plan, if you have a study injury or for any other reason. If you experience any of the following side effects: worsening of fecal incontinence symptoms, any intolerable side effects, or if you become ill during the study, you may have to be discontinued, even if you would like to continue.

PERSONS TO CONTACT ABOUT THIS STUDY

In the event that you have a question about the research experience, a research related injury or an adverse reaction (a side effect), please immediately contact the investigators on this study: **Felix Leung, M.D. at 818-891-7711, X32520, or you may call the hospital operator and ask to have Dr. Leung paged at X3074. In an emergency, you should call 911.**

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Greater Los Angeles Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Greater Los Angeles IRB at 1-310-268-4437 if you have questions, complaints or concerns about the study, or if you would like to obtain information or offer input.

SIGNIFICANT NEW FINDINGS

Sometimes during the course of a research study, new information becomes available that might change a person's decision to stay in the study. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your research doctor will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. If so, he or she will explain the reasons and arrange for your usual medical care to continue.

PAYMENT TO INVESTIGATORS

No salary support is requested for the investigators.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. Felix W. Leung has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

You voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record if applicable.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date

RIGHTS OF HUMAN SUBJECTS IN MEDICAL EXPERIMENTS

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 the procedure 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 any signed and dated written consent form used in relation to the experiment.

10. Be given an 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.