

CONSENT TO TAKE PART IN A RESEARCH STUDY

This is a research study for people who voluntarily choose to take part. Please take your time to make a decision, and discuss the study with your personal doctor, family and friends if you wish.

STUDY TITLE: THE EFFECT OF ADDING HIGH DOSE SIMETHICONE TO A STANDARD POLYETHYLENE GLYCOL PREPARATION ON ADENOMA DETECTION RATE DURING SCREENING COLONOSCOPY: A RANDOMIZED CONTROLLED PILOT TRIAL

INVESTIGATOR(s): *Antonio Mendoza Ladd, MD - Principal Investigator
Marc Zuckerman, MD – Co-Investigator
Mohammad Bashashati- Co-Investigator
Sharareh Moraveji, MD -Co-Investigator
Marco Bustamante, MD – Co-Investigator
Cesar J. Garcia, MD – Co-Investigator
Nancy Casner MS, CCRC - (study coordinator)*

CONTACT TELEPHONE NUMBERS:

You may contact the investigator at this number: 915 521 7843 during normal business hours if you develop any of the conditions listed in Question #8 of this form or if you have any unexpected complications.

INSTITUTION: *University Medical Center El Paso, Texas Tech University Health Sciences Center El Paso*

- 1. Why is this study being done?** *This study is being done in order to decide if adding simethicone to GoLYTELY (PEG-3350) the standard screening colon preparation decreases the amount of bubbles present in the colon at the time of colonoscopy, making it easier for the doctor to see any abnormalities in the lining of the colon.*
- 2. How many people will take part in this study?** *Approximately 375 patients will be included in this study; approximately 150 patients are planned to be in each of the 2 groups.*
- 3. Why am I being asked to take part in this research study?** *You are being asked to be in this study because you are between the ages of 30-75 and are scheduled to have a screening colonoscopy.*
- 4. What will happen during this study?** *There will be 2 groups of patients. One group will take simethicone along with the GoLYTELY and the other group will just take the GoLYTELY. You will choose an envelope and be assigned to the group in a randomized manner, like flipping a coin, a 1:1 ratio. The doctor performing the colonoscopy will not know the group you are in. The results of the colonoscopies in both groups will be compared to decide if adding simethicone to the GoLYTELY made any difference in the amount of bubbles seen in your colon by the doctor performing the colonoscopy.*
- 5. What will be done that is different from my usual care?** *You may be asked to take a dose of simethicone with your colonoscopy preparation if you are assigned to that group. You will complete a brief questionnaire regarding your preparation before the colonoscopy. In addition to the usual information collected from the medical record: your age, gender, ethnicity, past medical and surgical history data relating to your colonoscopy finding will also be collected.*

6. **How much of my time will this study take? How long will I be in the study?** *The only extra time that you will need to be in the study is about 5 minutes which is the time to answer the questionnaire.*
7. **Are there any benefits to me if I take part in this study?** *There is no guarantee that there will be any benefit. However, if the addition of simethicone improves the quality of the colonoscopy preparation you may benefit by having more polyps detected and/or removed by the doctor performing your colonoscopy, therefore decreasing your chances of getting colon cancer in the future.*
8. **What are the risks and/or discomforts to me if I join this study?** *The risks of participating in this study are the same as those of getting a standard screening colonoscopy. These are a 1 in 10,000 chance of bleeding or having a tear in your colon that requires emergency surgery and the risks related to the sedation such as (breathing) problems or aspiration pneumonia (inhaling gastric contents into your lungs that can cause infection) Other risks are the possible such as allergic reactions to simethicone but these are unlikely since it is a standard medication that is used even in babies to prevent indigestion..*

GoLYTELY should be used with caution in patients with arrhythmias, seizures, chronic kidney disease or reduced kidney function. If you suffer from one of these conditions notify the nurse and/or the doctor.

There may be other risks that are unknown.

9. **Will there be any added risks to me from this study if I am a female?** *No*
10. **What other choices do I have if I do not take part in the research study?** *This study does not involve treatment. You do not have to take part in this study.*
11. **What about confidentiality and the privacy of my records?**
We will keep your involvement in this research study confidential to the extent permitted by law. In addition to the staff carrying out this study, others may learn that you are in the study. This might include federal regulatory agencies such as the Food and Drug Administration (FDA) and the Office for Human Research Protection (OHRP), Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) representatives, representatives from any hospital or site where the research takes place, and the TTUHSC El Paso Institutional Review Board (a committee that reviews and approves research). These people may review and copy records involving your participation in this research. A copy of this document may be placed in your medical record.

The results of the study that are used in publications or abstracts will not include your name.

12. **Who is funding this study?** *The department of Medicine at Texas Tech University Health Sciences Center El Paso is providing the space and supplies for this study. No one on the research staff will receive anything of value from other agencies, organizations, or companies to carry out this research.*
13. **Will it cost me anything to take part in this research study?** *No. If you are selected to take simethicone, we will provide it to you at no cost. The cost of the procedure is already being paid by either yourself or your insurance company.*
14. **Will I receive anything for taking part in this research study?** *No*
15. **Does anyone on the research staff have a personal financial interest in this study?** *No*

16. What if I am hurt by participating in this study?

Texas Tech University Health Sciences Center El Paso and University Medical Center El Paso do not offer to pay for or cover the cost of medical treatment for research related illness or injury. No funds have been set aside to pay or reimburse you in the event of such injury or illness unless specifically stated.

If you have a research related illness or injury, care will be available to you as usual, but you and/or your medical or hospital insurance company will be responsible for the cost of treatment. Before entering this study, you should check whether your insurance company might limit your insurance coverage if you take part in a research study.

17. What are my rights as a voluntary participant?

Taking part in this study is your choice. If you sign this form, it means that you choose to be in the study.

You may also choose not to be in this study. If you decide not to be in the study, it will not affect any medical care, benefits or rights to which you are entitled.

If new information becomes available during the study that may affect your willingness to take part in the study, you will be told.

18. Can I stop being in the study?

You may leave the study at any time. If you leave the study, we cannot remove any information we have collected to that point.

19. Can someone else end my participation in the study?

Under certain circumstances, the investigators, TTUHSC El Paso, or the study sponsor may decide to end your participation in this research study earlier than planned. This might happen because of unexpected events in the study.

20. What if I have questions?

For questions about this study, contact the Antonio Mendoza Ladd, MD the Principal Investigator, at 915 521 7843

If you would like to speak to someone who is not involved in the study about your rights as a participant, research-related injuries, or any other matter related to the study, you can call the TTUHSC EthicsPoint Hotline at 1-866-294-9352.

Or, you can file an EthicsPoint report online:

<https://secure.ethicspoint.com/domain/media/en/gui/44534/index.html>. Please choose the "Regulatory Compliance" option when making an online report.

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

Your signature indicates that:

- **this research study has been explained to you;**
- **you have been given the opportunity to ask questions and have received answers;**
- **you accept your responsibility to follow the instructions given to you by the research team regarding study participation and, if applicable, research medication;**
- **you agree to take part in this study.**

You will be given a signed copy of this form.

Printed Name of Subject

Signature of Subject

AM/PM

Date

Time

I have discussed this research study with the subject using language that is understandable and appropriate. I believe I have fully informed the subject of the possible risks and benefits, and I believe the subject understands this explanation. I have given a copy of this form to the subject.

Printed name of authorized research personnel who conducted the informed consent discussion

Signature of authorized research personnel who conducted the informed consent discussion

AM/PM

Date

Time

TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO
AUTHORIZATION TO USE AND/OR DISCLOSE YOUR PROTECTED HEALTH INFORMATION
for a RESEARCH STUDY

STUDY TITLE: THE EFFECT OF ADDING HIGH DOSE SIMETHICONE TO A STANDARD POLYETHYLENE GLYCOL PREPARATION ON ADENOMA DETECTION RATE DURING SCREENING COLONOSCOPY: A RANDOMIZED CONTROLLED PILOT TRIAL

This form is intended to tell you about the use and/or disclosure (sharing) of your personal **Protected Health Information** (PHI) if you decide to participate in the research study described on the previous pages. The health information about you that may be used or disclosed is described below. This information is usually found in your medical records. Only the health information about you that is needed for this research study will be used or disclosed. When you consider taking part in this research study, you are also being asked to give your permission for your Protected Health Information to be released from your doctors, clinics, and hospitals to the research personnel approved for this research study. This Authorization specifically relates to the research study described in the attached Informed Consent document.

1. This Authorization is valid indefinitely or until such time as legal requirements will allow this Authorization to be destroyed.
2. If you choose to cancel this Authorization, please give notice in writing to:

**TTUHSC El Paso Privacy Officer
Office of Institutional Compliance
5001 El Paso Drive
El Paso, TX 79905**

If you sign this Authorization, the following persons, groups or organizations may rely on this Authorization to disclose your Protected Health Information to the Principal Investigator and other research personnel who are conducting this Study:

- your treating physicians and healthcare providers and their staff,
- associated healthcare institutions and hospitals where you have or may receive care.

While this research study is in progress, the Principal Investigator or research personnel working on this study will inform you whether or not you will be allowed to see the research related health information that is created about you or collected by the research personnel prior to the end of the study. After the study is finished you may request this information as allowed by the TTUHSC El Paso Notice of Privacy Practices.

The Protected Health Information that you authorize to be used or disclosed for research purposes may include your current or future health information from some or all of your health records, including:

<ul style="list-style-type: none">• hospital records and reports• admission history, and physical examination• X-ray films and reports; operative reports• laboratory reports, treatment and test results (including sexually transmitted diseases, HIV or AIDS)• any other Protected Health Information needed by the research personnel listed above. <p>(* use separate form for disclosure of psychotherapy notes)</p>	<ul style="list-style-type: none">• immunizations• allergy reports• prescriptions• consultations• clinic notes• mental health records• alcohol/substance abuse records
--	--

For the purposes of this study, your Protected Health Information may need to be reviewed or disclosed to individuals or organizations within and/or outside of TTUHSC El Paso who sponsor, approve, assist with, monitor or oversee the conduct of research studies. This includes, but is not limited to, the TTUHSC El Paso Institutional Review Board, TTUHSC El Paso compliance reviews, the U.S. Food and Drug Administration (FDA) or governmental agencies in other countries. Some of these individuals or organizations may share your health information further, and your health information may not be protected by the same privacy standards that TTUHSC El Paso is required to meet.

If you choose to sign this Authorization form, you can change your mind about this later. If you change your mind, send a letter to the person identified above telling us to stop collecting and sharing your Protected Health Information. When we receive your request, you may be asked to leave the research study if all the necessary information has not been collected. We may still use the information about you that we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

You have the right to refuse to sign this form. If you choose not to sign this form, your regular health care will not be affected. However, not signing this form will prevent you from participating in this research study and prevent you from receiving research related health care services provided under this study.

I have had the opportunity to review and ask questions regarding this Authorization to use or disclose my personal health information, and I will receive a copy of this form. By signing this Authorization, I am confirming that it reflects my wishes.

Printed Name of Subject

Signature of Subject

Date