Central Virginia Veterans Affairs Health Care System (CVHCS)
McGuire Institutional Review Board
Consent Form

Template Version Date: (6/15/2021)

Title of Research Study: A Single-Center, Randomized, Prospective, Single-Blinded study to Assess the Safety, Quality, and Tolerance of a Bowel Preparation Using a Food Kit with Laxatives in a United States Veteran Population

Sponsor: Investigator Initiated with Support from Happy Colon Foods

Investigator Name & Address: Joseph Spataro, MD; Department of GI/Hepatology; 1201 Broad Rock Boulevard; Richmond VA 23249

KEY INFORMATION:

We are asking you to consider participation in this research study which will investigate the safety, effectiveness, and how well people tolerate a food and laxative kit called Happy Colon Food Kit with Laxatives which is used as a bowel preparation (bowel prep) for colonoscopy. The Happy Colon Food bowel prep will be compared to the standard bowel prep clear liquid diet and polyethylene glycol 3350 (PEG-3350). This initial information is provided to help you decide whether or not to participate in the study.

Your participation in this study will include 1 study clinic visit before your scheduled colonoscopy procedure. The study clinic visit will involve questions about your health and medications and instructions for use of your assigned bowel prep regimen, and will last less than 1 hour. Specific details about the study clinic visit are provided below in Section 3.

You may want to participate in this study because the study bowel prep may be as effective and more tolerable as compared to the standard bowel prep. You may not want to participate because study bowel prep may not be as effective at cleaning your colon or because of the extra time involved in study participation. You may choose not to enroll in the study and you will receive the standard bowel prep for colonoscopy.

Additional detailed information is provided for your review in the sections below. Ask the research team questions until you feel you have enough information to make your decision about whether to participate. Participating in this research study is completely voluntary. Your decision to participate or not will have no effect on any of the services, benefits or rights to which you are otherwise entitled.

Happy Colon Foods is supplying the bowel prep kits used in this study.

The person in charge of this study is Dr. Joseph Spataro and he can be reached at (804) 675-5021. Other important contact information is listed below.

1. Whom should I contact for questions?
If you have any questions, concerns or complaints regarding this study, unexpected reactions, or you are injured and become ill as a result of participation in this study please call AM or PM*:*

	Office	**Off Hours**
Dr. Joseph Spataro	**(804) 675-5000 Ext. 2825**	**(804) 675-5000 Ext. 2825**
Research Staff	**(804) 675-5000, x5263 or x2568**	

If you are unable to reach any of the study staff listed and need immediate medical assistance, please call the McGuire VA Medical Center operator at **(800) 784-8381** and ask for the Emergency Room physician to obtain advice or call the **Emergency Room directly at (804) 675-5527**. If you have any questions, concerns or complaints about your rights as a research subject you may contact the **McGuire Institutional Review Board (IRB) at (804) 675-5676.** The IRB is responsible for reviewing research in humans and making sure that their safety and rights are protected.

2. What is this research study about?
You are being asked to participate in this research study because you are scheduled for a colonoscopy for colorectal cancer screening. The main purpose of this research study is to learn if an alternative bowel prep for colonoscopy is safe, tolerable and effective as compared to the standard bowel prep.

There is an equal chance that you will be assigned to receive either the standard bowel prep or the Happy Colon Foods Bowel Prep as described below. Assignment is done randomly (by chance) by computer. The study doctor will not know which bowel prep you have been assigned to receive.

- Standard Bowel Prep which includes a clear liquid diet the day before the colonoscopy and two doses of a laxative, PEG-3350 taken with about 1 gallon of water.
- Happy Colon Foods Bowel Prep which begins the day before the colonoscopy and contains foods that are easily digested and absorbed, and laxatives including PEG-3350 taken with about 1 gallon of water, senna tablets, and one dose of magnesium citrate.

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Approximately 130 subjects will participate in this study. Dr. Joseph Spataro is conducting this study here at McGuire VA Medical Center.

3. What is expected of me?
If you agree to participate, you will be asked to sign this consent form before any study procedures are done. The tests and procedures described below are being done for the purposes of this research.

Screening (to see if you are eligible to participate)

- You will be asked about your current health, and your past medical and surgical history.
- You will be asked about any medications (prescription or over the counter) that you are currently taking.
- You will be asked about your past and current use of tobacco.
- Your height and weight may be measured.
- Females will be asked if there is a chance you could be pregnant. If you are pregnant, you may not participate.

If you are eligible to participate in the study after Screening, you will be assigned to receive either the current standard bowel prep or the Happy Colon Food Kit bowel prep.

Study staff will provide you with the assigned bowel prep which you will begin the day before colonoscopy and complete the day of your colonoscopy. The study staff will discuss the instructions for the bowel prep in more detail with you, and you will be provided with written instructions.

You will receive a phone call about a week before your colonoscopy and instructions will be reviewed with you, and you may ask any questions you may have.

Day of Colonoscopy Procedure

- You will be asked to complete a questionnaire about the bowel prep you used, that will take about 10 minutes to complete.

4. Future Use of Data/Samples
Your information collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies.

5. Will the research benefit me?
There is no direct benefit to you from participating in this study. However, the information we get from this study may help others undergoing colonoscopy in the future.

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6. What are my alternatives to being a research subject?
You will not receive treatment for any medical condition in this study. Your alternative is not to participate.

7. What are my risks?
Participation in this study may involve risks that are unknown at this time. You should let the study staff know about any changes in your health or any symptoms, side effects, complaints, illnesses or injuries you may have while you are participating in this study.

Subjects using either the Happy Colon food kit or the standard regimen used to cleanse the bowel for colonoscopy may experience abdominal pain, cramping, bloating, nausea, vomiting, loose and/or liquid stools, headaches, weakness, hunger and sleeping difficulties.

There is the risk that either the Happy Colon food kit or the standard bowel prep may not provide adequate bowel cleansing for the colonoscopy procedure, in which case the colonoscopy procedure may need to be repeated.

All drugs have the potential to cause allergic reactions including the drugs used in this study. Allergic reactions may be mild to severe, and include the following symptoms: chills, fever, skin rash, hives, itching, watery eyes, swelling, headache, difficulty breathing, difficulty swallowing, severely low blood pressure, organ failure, and death. Serious allergic reactions require immediate medical attention.

8. Will I get paid?
You will not be paid for your participation in this research study.

9. Will I have to pay?
You will not have to pay, and your insurance will not be billed for treatments or procedures that are part of this study. If you get a bill for research services, contact the study staff. Some Veterans are required to pay co-payments for medical care and services provided by CVHCS. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of the study.

10. Does pregnancy prevent me from participating?

For Females
Every effort will be made to have females enter this study, but pregnant women will not be enrolled.

11. What if I get injured?
A research-related injury is any injury or illness caused by procedures required by the study. In the event of a research injury, any CVHCS study participant will receive

necessary medical treatment to treat the research injury provided at no cost to you or your insurance. This care may be provided by CVHCS or arrangements may be made for care at another facility.

If you believe you have an injury resulting from your participation in this research study, you should contact your study team. If you want to speak to someone who is not a member of the study team to discuss problems, ask questions or voice concerns, you may call the McGuire IRB at (804) 675-5676.

This agreement does not include treatment for injury or illness that is not a result of the study drug or study procedures. To help avoid injury, it is very important to follow all study directions. You are not giving up any of your legal rights by signing this form, and you are not releasing this institution from liability.

12. Who Will See My Information?

The study team will put information about your participation in this study in your medical record. The confidentiality of your research records will be maintained according to professional standards of confidentiality and Veterans Health Administration (VHA). Records identifying you may be reviewed by the members of the research team, the Research and Development Committee and its sub-committees, accrediting agencies, officials from the VHA, the Office of Research Oversight, the VA Office of the Inspector General, CVHCS and other federal oversight and regulatory agencies such as the FDA, Office for Human Research Protections, and as required by law.

The information collected about you while you are in the study such as your name, age and social security number will be protected. Study records will be kept in locked filing cabinets and on computers protected with passwords. Information published about the results of this study will not identify you.

The study doctor will share any clinically relevant results of testing done for research purposes with you. You will not have access to your research-related health records while you are participating in this study.

13. Do I have to participate in this study, or can I withdraw from the study?

Participation in this study is voluntary and you may refuse to participate without penalty or loss of benefits to which you are otherwise entitled. The study staff will answer any questions you may have about the study. You are free to withdraw your consent and stop participation at any time. If you decide to withdraw from this study, you should contact Dr. Spataro to discuss termination of your participation. Stopping will in no way change the quality of care you receive now or in the future at this institution or your right to participate in other studies.

Any significant new findings that develop during the research study that may affect your decision to continue participating will be provided to you as soon as possible.

Your participation in this research study may be ended without your consent for the following reasons:

- If the study doctor believes, for any reason, that it is within your best interest
- If you develop side effects that are considered dangerous
- If you refuse to use the assigned bowel prep kit or fail to follow the study instructions
- If you become pregnant
- The McGuire IRB may end the study at any time.

14. Date of Consent Form Revision: May 23, 2022

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Subject Name:_____ **Date:**_____

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Principal Investigator*:* Joseph Spataro, MD **CVHCS:** Richmond

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the above.

Dr. **Spataro** (or an associate) has explained the study to me and answered all my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled. The results of this study may be published, but my records will not be revealed unless required by law. By signing below, I am agreeing to participate in this research study. I will receive a signed copy of this consent form.

_____ _____

Subject's Signature **Date**

_____ _____

Signature of Person Obtaining Informed Consent **Print Name** **Date**

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