Northwell Health

RESEARCH PROTOCOL

Protocol Title:	Does a preoperative bowel regimen change time to first bowel movement after robotic sacral colpopexy: A Randomized Controlled Trial
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IRB Number:	19-0802
ClinicalTrials.gov ID	NCT04197869

Guidelines for Preparing a Research Protocol

Instructions:

- You do not need to complete this document if you are submitting an *Application for Exemption* or *Application for a Chart Review*.
- Do not use this template if:
  - Your study involves an FDA regulated product. In this case, use the *Clinical Trial Protocol Template.*
  - Your study has a protocol from a sponsor or cooperative group. In this case, use the *Protocol Plus*.
  - Your study is a registry or repository for data and/or samples, In this case, use *Protocol Template – Registry Studies.* .
- If a section of this protocol is not applicable, please indicate such.
- Do not delete any of the text contained within this document.
- Please make sure to keep an electronic copy of this document. You will need to use it, if you make modifications in the future.
- Start by entering study information into the table above, according to these rules:
  - Protocol Title: Include the full protocol title as listed on the application.
  - Investigator: include the principal investigator's name as listed on the application form
  - Date Revised: Indicate the date at which the protocol was last revised
  - IRB Number: Indicate the assigned IRB number, when known. At initial submission, this row will be left blank.
- Once the table information in entered, proceed to page 2 and complete the rest of the form.

↓ Continue to next page to begin entering information about this study ↓

1. PREVIOUS STUDY HISTORY

Has this study ever been reviewed and rejected/disapproved by another IRB prior to submission to this IRB?

☒ No ☐ Yes – if yes, please explain:

2. BRIEF SUMMARY OF RESEARCH

- *The summary should be written in **language intelligible to a moderately educated, non-scientific layperson**.*
- *It should contain a clear statement of the rationale and hypothesis of your study, a concise description of the methodology, with an emphasis on what will happen to the subjects, and a discussion of the results.*
- *This section should be ½ page*

Constipation is a prevalent problem following urogynecological procedures. Patients suffering from constipation are more often bearing down, which increases their risk of pelvic organ prolapse. It severely impacts patient quality of life, post-operative pain as well as recovery. No standardized pre or post-operative bowel regimen exists for patients undergoing urogynecology procedures. There is a need for a simple bowel regimen which can increase patient compliance and decrease time and pain with first post-operative bowel movement. This study could potentially uncover a simple and low risk intervention, which could positively impact patient care. While, previous studies focused on post-operative bowel regimens, this study aims to take a novel approach in pre-operative interventions. The study subjects will be exposed to a low risk medication, which could make a substantial difference in their post-operative pain, comfort and recovery.

The hypothesis is that starting a bowel regimen with Polyethylene Glycol prior to robotic assisted sacrocolpopexy will decrease time to first bowel movement after surgery. The experimental group will take a pre-operative course of polyethylene glycol daily for seven days prior to procedure date. The control group will not be given any intervention preoperatively. All patients will take polyethylene glycol postoperatively.

In order to assess bowel characteristics and assess for pre-existing constipation a standardized questionnaire will be distributed to all patients prior to surgery at their pre-operative visit. The patients in the experimental group will have follow up via phone call, 3-4 days prior to surgery to assess for medication compliance or any side effects/complications. Patients will record if they are taking their Miralax as prescribed daily. They will also record their bowel movements and pain levels

during evacuation. Prior to surgery, in the pre-operative area, medication compliance will be assessed once again. Post operatively all patients will take polyethylene glycol for seven days, once a day. They will maintain a bowel diary, which will record bowel movements, stool type and pain with evacuation. Prior to discharge from the hospital, subjects will be reminded to fill out the bowel diary and return it to the study team. The primary objective is to determine if the preoperative use of polyethylene glycol decreases time to first bowel movement after robotic sacral colpopexy. Secondary outcomes include pain with first bowel movement, stool consistency and daily pain levels.

3. INTRODUCTION/BACKGROUND MATERIAL/PRELIMINARY STUDIES AND SIGNIFICANCE

- *Describe and provide the results of previous work by yourself or others, including animal studies, laboratory studies, pilot studies, pre-clinical and/or clinical studies involving the compound or device to be studied.*
- *Include information as to why you are conducting the study and how the study differs from what has been previously researched, including what the knowledge gaps are.*
- *Describe the importance of the knowledge expected to result*

Constipation is a prevalent problem in the United States and is more commonly seen in women[1]. An epidemiologic study of constipation identified it as an inability to evacuate stool completely and spontaneously three or more times per week[1]. A significant correlation was noted between constipation and posterior genital prolapse[2]. Of POP patients, 24-52% complain of difficulties in defecation[2]. Increased bearing down pressure to evacuate stool during constipation produces anatomic changes in the pelvic floor[3], which increases the risk for prolapse. Constipation causes significant discomfort post-operatively following urogynecological procedures. A pre-operative medication regimen can decrease constipation, which in turn can work to reduce prolapse recurrence.

Prolonged time to first bowel movement after surgery impacts patient comfort levels, increases post-operative pain and causes anxiety[4]. Prior investigations reveal that among gynecologic surgical patients, the first bowel movement after surgery typically does not occur until 2 to 4 days postoperatively[4]. There is no established generally accepted regimen used to minimize postoperative defecatory discomfort in those undergoing gynecologic surgery[4]. Previous studies recognized these issues and aimed at finding a bowel regimen to aid in decreasing defecatory discomfort postoperatively.

The aim of this study is to take a novel approach and find a pre-operative bowel regimen. Patients in the experimental group will receive a seven-day pre-operative treatment with polyethylene glycol, and patients in both arms will take polyethylene glycol post-operatively as part of their routine clinical care. Polyethylene glycol has been studied and proven to be safe and effective in aiding

with constipation. This regimen offers a simple and novel approach which could potentially decrease constipation and post-operative pain and patient discomfort. This could ultimately aid in decreasing recurrent prolapse rates.

4. OBJECTIVE(S)/SPECIFIC AIMS AND HYPOTHESES

- *A concise statement of the goal(s) of the current study.*
- *The rationale for and specific objectives of the study.*
- *The goals and the hypothesis to be tested should be stated.*

The primary objective of this study is to assess whether a pre-operative treatment with a laxative will decrease the time to first bowel movement following a robotic sacrocolpopexy. The secondary objective of the study is to assess for pain with first bowel movement, stool consistency and daily pain levels.

5. RESOURCES AVAILABLE TO CONDUCT THE HUMAN RESEARCH

- *Explain the feasibility of meeting recruitment goals of this project and demonstrate a potential for recruiting the required number of suitable subjects within the agreed recruitment period*
    - *How many potential subjects do you have access to?*
- *Describe your process to ensure that all persons assisting with the trial are adequately informed about the protocol and their trial related duties and functions*

The Suffolk Urogynecology practice performs approximately 100 robotic assisted sacrocolpopexies per year. The recruitment period will last around 3 years, given the amount of such operations and the need for 24 patients in each study arm. This time period also accounts for a patient dropout rate of 20%. All patients who are eligible and meet inclusion criteria will be offered participation in the study during their preoperative patient visit. In order for all persons assisting with the trial to be adequately informed, several meetings will take place to clarify goals, roles and expectations of all team members.

6. RECRUITMENT METHODS

- *Describe the source of potential subjects*
- *Describe the methods that will be used to identify potential subjects*
- *Describe any materials that will be used to recruit subjects. A copy of any advertisements (flyers, radio scripts, etc.) should be submitted along with the protocol.*
- *If monetary compensation is to be offered, this should be indicated in the protocol*

Suffolk Urogynecology patients who are planning on undergoing a robotic assisted sacrocolpopexy will be screened preoperatively and offered participation in the study during their office visit. If a patient meets inclusion criteria, then the study

purpose and design will be explained to the patient. No monetary compensation will be offered. No advertisements will be used.

7. ELIGIBILITY CRITERIA

- *Describe the characteristics of the subject population, including their anticipated number, age, ranges, sex, ethnic background, and health status. Identify the criteria for inclusion or exclusion of any subpopulation.*
- *Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners or other institutionalized individuals, or others who are likely to be vulnerable. You cannot include these populations in your research, unless you indicate such in the protocol*
- *Similarly, detail exclusionary criteria: age limits, special populations (minors, pregnant women, decisionally impaired), use of concomitant medications, subjects with other diseases, severity of illness, etc.*

The subject population consists mostly of healthy, pre and postmenopausal females. The majority of the patients are Caucasian, with a small percentage of Hispanic and African American patients. Study consents will be available in English and Spanish languages. Patients whose preferred language is not English or Spanish will not be offered participation in the study. All patients will be cleared for surgery preoperatively by their primary medical doctor.

Inclusion criteria are the following: patients undergoing a robotic assisted sacrocolpopexy with or without hysterectomy and with or without anti-incontinence procedures.

Exclusion criteria are the following: age under 18 or over 90, planned laparotomy, planned posterior colporrhaphy, regular pre-operative use of stool softeners/laxatives, presence of colostomy, inability to give informed consent, inability to take medication by mouth, chronic kidney disease (Cr > 1.2), esophageal strictures, persistent nausea and vomiting, bowel obstruction, and inflammatory bowel disease. Special subjects, minors or vulnerable individuals are not to be included in the study. Minorities will be offered participation.

8. NUMBER OF SUBJECTS

- *Indicate the total number of subjects to be accrued locally. If applicable, distinguish between the number of subjects who are expected to be pre-screened, enrolled (consent obtained), randomized and complete the research procedures.*
- *If your study includes different cohorts, include the total number of subjects in each cohort.*
- *If this is multisite study, include total number of subjects across all sites.*

We anticipate pre-screening approximately 110 patients. 24 subjects are needed in each study arm, but 36 subjects will be randomized to account for the 34% drop out

rate. The study will be done with patients who are being treated at Suffolk Urogynecology which includes three attending physicians and four different outpatient offices located in Plainview, Bay Shore, Huntington and Wading River. The distribution of subjects across sites is anticipated to be even. We expect 66% of patients to complete the study.

9. STUDY TIMELINES

- *Describe the duration of an individuals participation in the study*
- *Describe the duration anticipated to enroll all study subjects*
- *The estimated date of study completion*

The individuals will be offered participation in the study during their regular scheduled pre-operative appointment within 90 days of their surgery date. Those who agree to participate will sign consent for the study at that time and fill out the pre-operative questionnaire. The patients will go home with 2 different packets of bowel diaries (one for the experimental arm and one for the control). 7-14 days prior to their surgery date the patients will be randomized to one of two groups and they will receive a phone call to notify them of which group they are in and whether or not they will be taking Miralax pre-operatively. Prior to discharge from the hospital, subjects will be reminded to fill out the bowel diary and return it to the study team. The patients will attend a follow up visit 7-14 days after their surgery, which will be in accordance to their standard of care. The total duration of their participation in the study will be approximately 4 months. The anticipated duration to enroll all study subjects is 3 years. The estimated date of study completion is December of 2022.

10. ENDPOINTS

- *Describe the primary and secondary study endpoints*
- *Describe any primary or secondary safety endpoints*

The primary study endpoint will be time of the first post-operative bowel movement. Safety endpoints will include: persistent nausea and vomiting, more than 3 lose bowel movements a day. There are no secondary safety end points.

11. RESEARCH PROCEDURES

- *Include a detailed description of all procedures to be performed on the research subject and the schedule for each procedure.*
- *Include any screening procedures for eligibility and/or baseline diagnostic tests*
- *Include procedures being performed to monitor subjects for safety or minimize risks*
- *Include information about drug washout periods*
- *If drugs or biologics are being administered provide information on dosing and route of administration*
- *Clearly indicate which procedures are only being conducted for research purposes.*

- *If any specimens will be used for this research, explain whether they are being collected specifically for research purposes.*
- *Describe any source records that will be used to collect data about subjects*
- *Indicate the data to be collected, including long term follow-up*

The research subjects will be randomized to a control group that receives no medications pre-operatively and an experimental group which receives polyethylene glycol once a day for seven days pre-operatively. All subjects will be enrolled during their pre-operative visit within 90 days of their scheduled surgery (as is standard of care), and they will be asked to fill out a pre-operative questionnaire regarding their bowel habits. All patients will also complete a pre-operative bowel diary indicating a number on the pain scale with their bowel movements for the 7 days leading up to surgery. They will record information about their first post-operative bowel movement, such as: time, date, pain with and consistency of. They will record a daily pain level post-operatively. Patients will have telephone follow up to assess their symptoms 3-4 days after surgery. All patients will record their use of pain medication pre and post operatively. In addition, the patients in the group receiving Miralax will also fill out a form indicating if they have taken their daily dose of Miralax pre-operatively. They will also have a telephone follow up to assess their symptoms 3-4 days before surgery. Prior to discharge from the hospital, subjects will be reminded to fill out the bowel diary and return it to the study team.

Polyethylene Glycol 3350 17g should be mixed in 8 ounces of fluid for administration. Polyethylene glycol is a high molecular weight, water soluble polymer which can form hydrogen bonds with water molecules.[5] It is an osmotic laxative solution which stimulates bowel movements by increasing the amount of water absorbed in the GI tract. It decreases feces consistency and increases their volume by promoting peristalsis and evacuation.[5] The side effects of polyethylene glycol are bloating, gas or diarrhea. The half-life of polyethylene glycol is 4-6 hours and after 18 hours the concentration declines to non-quantifiable levels.[6]

The pre-operative 7 day polyethylene glycol regimen for the experimental group will be conducted for research purposes, as well as the questionnaires and bowel diaries. The remainder of the patients' treatment will not be done as part of the research trial and will adhere to the usual standard of care (including the pre and postoperative visits). Data will be collected from the Allscripts and Sunrise EMRs as well as in the form of questionnaires and bowel diaries. This data will be kept on RedCap. Subject names and initials, elements of date, telephone and medical record numbers will be collected from the EMR and recorded in RedCap. All other patient identifiers will be accessed in the EMR, but not recorded such as: address, fax number, email address and health plan beneficiary number.

12. STATISTICAL ANALYSIS

- *Describe how your data will be used to test the hypotheses.*

- *State clearly what variables will be tested and what statistical tests will be used.*
- *Include sample size calculations.*
- *If this is a pilot study, state which variables will be examined for hypothesis generation in later studies.*

The post-operative bowel diary will provide the time to first bowel movement of each patient and the data will be averaged for the control and experimental groups. Other variables to be tested will be: pain with first bowel movement, stool consistency and daily pain levels. Patient will undergo a 1:1 randomization 7-14 days prior to their scheduled surgery date.

For continuous outcomes, such as the primary endpoint, (time to observe the first bowel movement after surgery) 2-sample t test (given large sample size) or Wilcoxon rank-sum test (given smaller sample size) will be used to compare the difference between the control and treatment groups. For categorical outcomes, chi-sq test or Fisher's exact test will be used to determine the difference between the control and treatment groups. A significant level of 0.05 will be used for all statistical tests. All data manipulation will be carried out by the department biostatistician using RStudio Version 1.1.463 5 (built on R version 3.5.1).

Sample size calculation: Previous research conducted by McNanley et al. [4] suggested an average of 3.6 ± 1.2 days to observe the first bowel movement after robotic sacrocolpopexy. Therefore, in order to observe a delta=1 day (24hr) shorter time post-surgery, we calculated that a sample size of 24 patients per study randomization group is needed at a significance level 0.05 and power level 0.8 (delta represents the time you expect to shorten with polyethylene glycol treatment).

13. SPECIMEN BANKING

- *If specimens will be banked for future research, describe where the specimens will be stored, how long they will be stored, how they will be accessed and who will have access to the specimens*
- *List the information that will be stored with each specimen, including how specimens are labeled/coded*
- *Describe the procedures to release the specimens, including: the process to request release, approvals required for release, who can obtain the specimens, and the information to be provided with the specimens.*

N/A

14. DATA MANAGEMENT AND CONFIDENTIALITY

- *Describe the data and specimens to be sent out or received. As applicable, describe:*

- *What information will be included in that data or associated with the specimens?*
- *Where and how data and specimens will be stored?*
- *How long the data will be stored?*
- *Who will have access to the data?*
- *Who is responsible for receipt or transmission of data and specimens?*

- *Describe the steps that will be taken to secure the data during storage, use and transmission.*

The data obtained in this study will be stored on RedCap in an electronic online HIPAA compliant format. It will be data based off the questionnaires completed by the patients. The data will be stored for a period of 10 years after the completion of the study. Only the study investigators will have access to the data. Alexandra Goodwin will be responsible for the receipt and transmission of data. The data storage in RedCap will be under personal password protection.

15. DATA AND SAFETY MONITORING PLAN

A specific data and safety monitoring plan is only required for greater than minimal risk research. For guidance on creating this plan, please see the Guidance Document *on the HRPP website.*

Part I – this part should be completed for all studies that require a DSMP.
Part II – This part should be completed when your study needs a Data and Safety Monitoring Board or Committee (DSMB/C) as part of your Data and Safety Monitoring Plan.

Part I: Elements of the Data and Safety Monitoring Plan

- *Indicate who will perform the data and safety monitoring for this study.*
- *Justify your choice of monitor, in terms of assessed risk to the research subject's health and well being. In studies where the monitor is independent of the study staff, indicate the individual's credentials, relationship to the PI, and rationale for selection*
- *List the specific items that will be monitored for safety (e.g. adverse events, protocol compliance, etc)*
- *Indicate the frequency at which accumulated safety and data information (items listed in # above) will be reviewed by the monitor (s) or the DSMB/C.*
- *Where applicable, describe rules which will guide interruption or alteration of the study design.*
- *Where applicable, indicate dose selection procedures that will be used to minimize toxicity.*
- *Should a temporary or permanent suspension of your study occur, in addition to the IRB, indicate to whom will you report the occurrence.*

Dr. Danielle O'Shaughnessy will perform the data and safety monitoring for this study. She is a Urogynecology attending involved in the study. She is an expert in the field and has access to patient records. The risks to the research subjects are minimal.

Data and Safety Monitoring Plan (DSMP)

The PI will identify a Safety Officer with expertise in Urogynecology who does not have any financial conflict of interest related to the study. Safety will be formerly monitored every 6 months by the study team and the Safety Officer throughout the duration of the study. Dr. Goodwin will prepare a safety report for these regular reviews comprised of anticipated safety events and actions taken. The PI will contact the Safety Officer for ad hoc reviews of any unanticipated safety events. The study protocol will be carried out in accordance with IRB guidelines and requirements. In the event of a serious adverse event during the study protocol, it will be reported immediately to the PI, the co-investigators, and the Safety Officer. It will also be reported to the IRB and to all members of the research team. With the approval of the participants and families, the information will be provided to other care providers as directed.

Risk Assessment

The primary concern is the development of adverse side effects to polyethylene glycol.
Subjects will be monitored throughout the study for these potential adverse events by: assessing their symptoms and their tolerance to the medication administered. This will be monitored by phone calls before and after surgery, as well as in the pre-operative area. Symptoms and the development of any adverse effects will be assessed at least 3 times per each study individual every few days.
The PI (or another designated Investigator in his absence) will be notified of any abnormal results so that the safety measures outlined below are implemented. The consenting physicians will also be notified of any abnormal results and any changes to the subject's care, and will also be provided with the test results. The potential risks and protections are as follows:

1. Adverse side effects to polyethylene glycol:

- Monitoring: Phone calls to the patient every few days
- Actions:
  - If the subjects report an allergic reaction to polyethylene glycol at screening, subject will not be enrolled.
  - If the subjects report adverse symptoms or side effects such as: diarrhea, gas or pain causing discomfort at any study point, subject will be taken off therapy, but will continue to be followed until end of study.
  - If the subject complains of symptoms concerning for rectal bleeding she will be checked and undergo any additional clinical testing requested by primary physician.

Part II: Data and Safety Monitoring Board or Committee

- *When appropriate, attach a description of the DSMB.*
- *Provide the number of members and area of professional expertise.*
- *Provide confirmation that the members of the board are all independent of the study.*

N/A

16. WITHDRAWAL OF SUBJECTS

- *Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent*
- *Describe procedures for orderly termination*
- *Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*

Subjects will be withdrawn from the research if they develop any adverse reactions to the medication. Should early termination occur, the subject as well as the research team will be made aware and the data will be recorded accordingly.

17. RISKS TO SUBJECTS

- *Describe any potential risks and discomforts to the subject (physical, psychological, social, legal, or other) and assess their likelihood and seriousness and whether side effects are reversible. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.*
- *Include risks to others , like sexual partners (if appropriate)*
- *Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to results*
- *Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness.*

The intervention that the experimental group would be undergoing is taking a laxative (polyethylene glycol) for seven days prior to surgery. The potential common side effects from polyethylene glycol include; bloating, cramping, gas, and diarrhea which may lead to dehydration. The subjects will be monitored for potential side effects via phone call prior to the surgery. The medication could be discontinued depending on the side effects and patient satisfaction. This is a standard laxative used for patient post-operatively and is known to be well tolerated. The possible side effects are not life threatening and will mostly cause discomfort. They are also reversible with cessation of the medication. We do not anticipate any psychological, social or legal side effects. The risks that this medication poses are minor, but the benefits could be major. Constipation is a common post-operative problem that has been known to cause a great deal of pain and discomfort. If pre-operative polyethylene glycol shows benefit in improving those symptoms, then a patient's post-operative recovery could potentially be

quicker and less painful. This is a relatively simple and low risk intervention which could make a significant patient satisfaction impact. In order to minimize the risks and protect patients, the study investigators will call patients once they begin taking pre-operative polyethylene glycol to assess for any side effects or discomfort. The medication will be stopped if any adverse effects are seen.

18. RESEARCH RELATED HARM/INJURY

- *Describe the availability of medical or psychological resources that subjects might need as a result of anticipated problems that may be known to be associated with the research.*
- *If the research is greater than minimal risk, explain any medical treatments that are available if research-related injury occurs, who will provide it, what will be provided, and who will pay for it.*

The Suffolk Urogynecology practice will be available by phone or for appointment to discuss any medical or psychological issues at the time of the trial. Treatment will be provided to the patient if necessary. Appropriate referrals will be made if a necessary type of treatment or expertise is not available. If patients develop side effects, cessation of the medication will provide necessary resolution.

19. POTENTIAL BENEFIT TO SUBJECTS

- *Explain what benefits might be derived from participation in the study, noting in particular the benefit over standard treatment (e.g. a once-a-day administration instead of four times a day, an oral formulation over an IV administration).*
- *Also state if there are no known benefits to subjects, but detail the value of knowledge to be gained*

This study may not benefit the subjects directly. However, if the pre-operative polyethylene glycol regimen proves to decrease time to first bowel movement, as well as decrease post-operative pain and discomfort, then the patients in the experimental arm may benefit from participation in the study. This study could also provide knowledge in creating a helpful pre-operative regimen as a standard of care for future patients because currently a standard treatment does not exist.

20. PROVISIONS TO PROTECT PRIVACY INTERESTS OF SUBJECTS

- *Describe the methods used to identify potential research subjects, obtain consent and gather information about subjects to ensure that their privacy is not invaded.*
- *In addition consider privacy protections that may be needed due to communications with subjects (such as phone messages or mail).*

Potential research subjects will be identified during their pre-operative visit with the Suffolk Urogynecology practice, using the inclusion and exclusion criteria. During this visit, consent will be obtained and the study design explained. Communication with patients will occur in the office in a private setting to ensure confidence. Follow ups will occur via phone and privacy will be ensured when speaking to the patient.

21. COSTS TO SUBJECTS

- *Describe any foreseeable costs that subjects may incur through participation in the research*
- *Indicate whether research procedures will be billed to insurance or paid for by the research study.*

Patients who choose to participate in the study, will be asked to purchase Miralax over the counter. All patient pre and post-operative visits will be part of their standard of care regardless of study participation.

22. PAYMENT TO SUBJECTS

- *Describe the amount of payment to subjects, in what form payment will be received and the timing of the payments.*

Subjects will not receive payment for study participation.

23. CONSENT PROCESS

If obtaining consent for this study, describe:

- *Who will be obtaining consent*
- *Where consent will be obtained*
- *Any waiting period available between informing the prospective participant and obtaining consent*
- *Steps that will be taken to assure the participants' understanding*
- *Any tools that will be utilized during the consent process*
- *Information about how the consent will be documented in writing. If using a standard consent form, indicate such.*
- *Procedures for maintaining informed consent.*

Dr. Finamore, Dr. Pillalamarri and Dr. O'Shaughnessy will be obtaining consent for study participation in one of the four office locations of the Suffolk Urogynecology practice (Plainview, Bay Shore, Huntington and Wading River). Consent will be obtained once the patient agrees to study participation, without a waiting period unless the patient requests otherwise. The details of

the study will be explained and all questions answered to ensure participants' understanding. The consent form will be documented in writing explaining the details of the study as well as the risks and benefits of participation. Informed consent will be maintained by explaining the details of the study to each patient carefully. A standard consent form will be used.

In the state of NY, any participants under the age of 18 are considered children. If your study involves children, additional information should be provided to describe:

- *How parental permission will be obtained*
- *From how many parents will parental permission be obtained*
- *Whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. The process used to determine these individual's authority to consent for the child should be provided*
- *Whether or not assent will be obtained from the child*
- *How will assent be documented*
- *Whether child subjects may be expected to attain legal age to consent to the procedures for research prior to the completion of their participation in the research. If so, describe the process that will be used to obtain their legal consent to continue participation in the study. Indicate what will occur if consent is not obtained from the now-adult subjects.*

N/A.

If the study involves cognitively impaired adults, additional information should be provided to describe:

- *The process to determine whether an individual is capable of consent*
- *Indicate who will make this assessment*
- *The plan should indicate that documentation of the determination and assessment will be placed in the medical record, when applicable, in addition to the research record.*
- *If permission of a legally authorized representative will be obtained,*
  - *list the individuals from who permission will be obtained in order of priority*
  - *Describe the process for assent of subjects; indicate whether assent will be required of all, some or none of the subjects. If some, which subjects will be required to assent and which will not.*
  - *If assent will not be obtained from some or all subjects, provide an explanation as to why not*
  - *Describe whether assent will be documented and the process to document assent*
  - *Indicate if the subject could regain capacity and at what point you would obtain their consent for continued participation in the study*

N/A

If the study will enroll non-English speaking subjects:

- *Indicate what language(s) other than English are understood by prospective subjects or representatives*
- *Indicate whether or not consent forms will be translated into a language other than English*
- *Describe the process to ensure that the oral and written information provided to those subjects will be in that language*
- *If non-English speaking subjects will be excluded, provide a justification for doing so*

The study subjects will either be English or Spanish speaking. There will be English and Spanish consents available. The study will be explained to the patient in their preferred language and interpreter services will be used when necessary.

24. WAIVER OR ALTERATION OF THE CONSENT PROCESS [X] N/A

Complete this section if you are seeking an alteration or complete waiver of the consent process.

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to the subject:*
- *Explain why the waiver/ alteration will not adversely affect the rights and welfare of subjects*
- *Explain why it is impracticable to conduct this research if informed consent is required*
- *Explain why it is not possible to conduct this research without using the information or biospecimens in an identifiable form*
- *If appropriate, explain how the subjects will be provided with additional pertinent information after participation. If not appropriate to do so, explain why.*

N/A

Complete this section if you are obtaining informed consent but you are requesting a waiver of the documentation of consent (i.e., verbal consent will be obtained). *To proceed with a waiver based on these criteria, each subject must be asked whether they wish to have documentation linking them to this study.* ***Only complete subsection 1 OR subsection 2.***

SUBSECTION 1

- *Explain how the only record linking the subject to the research would be the consent document.*
- *Explain how the principal risk of this study would be the potential harm resulting from a breach in the confidentiality*

- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

N/A

SUBSECTION 2

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk.*
- *Confirm that the research only involves procedure for which consent is not normally required outside the research context.*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

N/A

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25. WAIVER OF HIPAA AUTHORIZATION [X] N/A

Complete this section if you seek to obtain a full waiver of HIPAA authorization to use and/or disclose protected health information.

- *Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy:*
- *Describe your plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time.*
- *Indicate why it is not possible to seek subjects' authorization for use or disclosure of PHI.*
- *Indicate why it is not possible to conduct this research without use or disclosure of the PHI.*
- *Indicate if PHI will be disclosed outside NSLIJ Health System, and if so, to whom. Note: PHI disclosed outside NSLIJ Health System, without HIPAA authorization needs to be tracked. Please see guidance at www.nslij.com/irb for information about tracking disclosures.*

N/A

Complete this section if you seek to obtain a partial waiver of the patient's authorization for screening/recruitment purposes *(i.e., the researcher does not have access to patient records as s/he is not part of the covered entity)*

Note: Information collected through a partial waiver for recruitment cannot be shared or disclosed to any other person or entity.

- *Describe how data will be collected and used:*
- *Indicate why you need the PHI (e.g.PHI is required to determine eligibility, identifiers are necessary to contact the individual to discuss participation, other)*

- *Indicate why the research cannot practicably be conducted without the partial waiver (e.g. no access to medical records or contact information of the targeted population, no treating clinician to assist in recruitment of the study population, other)*

N/A

26. VULNERABLE POPULATIONS:

Indicate whether you will include any of these vulnerable populations. If indicated, submit the appropriate appendix to the IRB for review:

- ☐ *Children or viable neonate*
- ☐ *Cognitively impaired*
- ☐ *Pregnant Women, Fetuses or neonates of uncertain viability or nonviable*
- ☐ *Prisoners*
- ☐ *NSLIJ Employees, residents, fellows, etc*
- ☐ *poor/uninsured*
- ☐ *Students*
- ☒ *Minorities*
- ☐ *Elderly*
- ☐ *Healthy Controls*

If any of these populations are included in the study, describe additional safeguards that will be used to protect their rights and welfare.

Hispanic patients will be included in the study and consents in Spanish will be available to the patients. Interpreter services will be used to ensure patient understanding.

27. MULTI-SITE HUMAN RESEARCH (COORDINATING CENTER)

If this is a multi-site study where you are the lead investigator, describe the management of information (e.g. results, new information, unanticipated problems involving risks to subjects or others, or protocol modifications) among sites to protect subjects.

N/A

28. REFERENCES/BIBIOGRAPHY

Provide a reasonable list of references directly related to the study. Any diagrams for new medical devices or brief reprints from journals might also prove useful.

1. Lembo, Anthony, and Michael Camilleri. *Chronic Constipation | NEJM*. 2 Oct. 2003, www.nejm.org/doi/full/10.1056/NEJMra020995.

2. Bove, Antonio. "Consensus Statement AIGO/SICCR Diagnosis and Treatment of Chronic Constipation and Obstructed Defecation (Part II: Treatment)." *World Journal of Gastroenterology*, vol. 18, no. 36, 28 Sept. 2012, pp. 4994–5013., doi:10.3748/wjg.v18.i36.4994.

3. Arya LA, Novi JM, Shaunik A, Morgan MA, Bradley CS. Pelvic organ prolapse, constipation, and dietary fiber intake in women: a case-control study. Am J Obstet Gynecol. 2005 May;192(5):1687-91. doi: 10.1016/j.ajog.2004.11.032. PubMed PMID: 15902178.

4. McNanley A, Perevich M, Glantz C, Duecy EE, Flynn MK, Buchsbaum G. Bowel function after minimally invasive urogynecologic surgery: a prospective randomized controlled trial. Female Pelvic Med Reconstr Surg. 2012 Mar-Apr;18(2):82-5. doi: 10.1097/SPV.0b013e3182455529. PubMed PMID: 22453316

5. Mínguez M, López Higueras A, Júdez J. Use of polyethylene glycol in functional constipation and fecal impaction. Rev Esp Enferm Dig. 2016 Dec;108(12):790-806. doi: 10.17235/reed.2016.4571/2016. Review. PubMed PMID: 27871178.

6. Pelham RW, Nix LC, Chavira RE, Cleveland MV, Stetson P. Clinical trial: single- and multiple-dose pharmacokinetics of polyethylene glycol (PEG-3350) in healthy young and elderly subjects. Aliment Pharmacol Ther. 2008 Jul;28(2):256-65. doi: 10.1111/j.1365-2036.2008.03727.x. Epub 2008 Apr 30. PubMed PMID: 18462266.