RESEARCH CONSENT FORM

Project Title: Designing optimal prevention and management of postoperative nausea and emesis for patients undergoing Laparoscopic Sleeve Gastrectomy.
Principal Investigator: Dr. Konstantinos Spaniolas[1].
Co-Investigators: Dr. Aurora Pryor[1], Dr. Daryn Moller[2] , Dr. Andrew Bates[1], Dr. Salvatore Docimo[1], Dr. Tyler Cohn[1], Darragh Herlihy NP[1].
Department: Surgery, Anesthesiology

You are being asked to be a volunteer in a research study.

PURPOSE

The purpose of this study is:

- Bariatric surgery remains the most effective therapy for obesity. Nausea and vomiting are commonly reported following bariatric surgery.
- The proposed study focuses on the laparoscopic sleeve gastrectomy (LSG) which is most common bariatric procedure performed. It aims to assess the effect of a specific intervention on post-operative nausea and vomiting.
- We hypothesize that the group that will receive this specific intervention will experience a reduction of prolonged hospital stay and significantly improve quality of recovery from surgery.
- Subjects undergoing surgery will be randomized to two groups: control vs Nausea specific-intervention group.
- An effect on the presence and degree of Post-operative Nausea and Vomiting will be measured by serial questionnaires of nausea, vomiting, quality of life and quality of recovery.
- The total sample size is 82.

PROCEDURES :

- **If you decide to be in this study, your part will involve:**
- You will be assessed in the outpatient clinic on the basis of inclusion and exclusion criterion. Patients enrolled in this study will be randomized by a computer generated number to controll group and Post-operative nausea and vomiting specific intervention group .
- All subjects will be assessed with a nausea specific questionnaire at 1, 4, 12, 24 hours and 3 weeks after surgery.
- Patient satisfaction with recovery will be assessed using specialized questionnaires at baseline, 24 hours and 3weeks following surgery.

RISKS / DISCOMFORTS

The following risks/discomforts may occur as a result of you being in this study:

The risk related to the conduct of this study is due to possible adverse events from medication use. All the medications proposed in this study are commonly used in the clinical setting for perioperative care, with minimal risk. The proposed study does not introduce a new therapy or medication in this clinical setting, but it attempts to assess a protocol of care for a specific patient population. In terms of each medication specifically, all the medications proposed are currently often used for the perioperative care of bariatric patients
(Aprepitant, Scopolamine, Dexamethasone, Ondansetron, Propofol, Sugammadex, and Promethazine). Serious adverse events are not common for any of the medications used in the study:

Aprepitant - The minor adverse events include hiccups, heartburn, diarrhea, headache, fatigue, constipation and abdominal pain.
Scopolamine – Contraindicated in patients with closed angle glaucoma. Adverse events are uncommon and can include hallucinations, confusion and dizziness. The most common is dry mouth, which is well tolerated in this patient population.
Ondansetron – The most common adverse events for ondansetron when used for prevention of postoperative nausea is headache and hypoxia. QT interval prolongation can occur, so patients with a history of congenital long QT syndrome will be excluded. This medication is used as first line for prevention and treatment of postoperative nausea for most patients.
Propofol - Common adverse events include cough, burning sensation around IV site, anxiety, muscle pain, urine discoloration; all of these are self-limited and non-serious. Hypotension related to propofol will be assessed for and treated in real-time by the anesthesiology team as per clinical practice.
Sugammadex - Use in patients with renal failure is not recommended, so patients with creatinine clearance less than 30 will be excluded from the study.
Compazine– The most common AEs include dizziness, drowsiness, anxiety;sleep problems (insomnia), strange dreams;dry mouth, stuffy nose , blurred vision , constipation, breast swelling or discharge, a missed menstrual period.

All medications will be administered in a monitored setting (tertiary care referral center). In current clinical practice, all these medications, often in combination, are being used for the prevention and treatment of postoperative nausea. AEs are not common, and are overall minor in severity.

Being a part of this study while pregnant may expose the unborn child to significant risks that are not justified, given the purpose of the study. Therefore, pregnant females will be excluded from the study. If you are a female who can become pregnant, a pregnancy test must be done, and must be negative before you can enter this study.

BENEFITS

There may be no direct benefit to you as a result of being in this study.

Our hope is that the study will provide valuable insight on the causes of post-operative nausea and vomiting after hospital discharge following Sleeve gastrectomy, which is currently poorly characterized. By allowing us to assess the overall incidence of nausea and vomiting at different time points, this study will afford us the opportunity to identify a time period of high incidence and further adjust our prevention efforts accordingly in future studies.

PAYMENT TO YOU: You will not be paid for this study.

PAYMENT TO THE INSTITUTION This project is funded, in part, by a grant or contract from The Research Committee of the Society for Surgery of the Alimentary Tract to the Research Foundation of Stony Brook University, in support of the Investigators' work on this study.

CONFIDENTIALITY

We will take steps to help make sure that all the information we get about you is kept confidential. Your name will not be used wherever possible. We will use a code instead. All the study data that we get from you will be kept locked up. The code will be locked up too. If any papers and talks are given about this research, your name will not be used**.**

We want to make sure that this study is being done correctly and that your rights and welfare are being protected. For this reason, we will share the data we get from you in this study with the study team, the sponsor of the study (and those who work for them), Stony Brook University's Committee on Research Involving Human Subjects, applicable Institutional officials, and certain federal offices, including the Office for Human Research Protections (OHRP), and, where applicable, the Food and Drug Administration (FDA). However, if you tell us you are going to hurt yourself, hurt someone else, or if we believe the safety of a child is at risk, we will have to report this.

In a lawsuit, a judge can make us give him the information we collected about you.

While you are in this study we will get data about your health from your medical record. We will also get health data from the results of the tests you will have done in this study. You have a right to privacy but the data we get about your health in this study can be shared with the people

referenced above (the study team, the sponsor of this study, those who work for the sponsor, Stony Brook University's Committee on Research Involving Human Subjects, applicable institutional officials, and federal offices such as OHRP, FDA) as well as:

- your insurance company
- your medical doctor

Your health data are shared to make sure the study is being done correctly, costs are charged correctly, and to make sure your rights and safety are protected. Not all of these people are required by law to protect your health data. They might share it with others without your permission but no identifiers will be used.

You have the right to stop allowing us to use or give out your health data. You can do this at any time by writing to Dr. Konstantinos Spaniolas. If you do this, we will stop collecting any new health data from you, except if we need to keep an eye on a bad side effect you were having in the study. We will use any data we collected before you wrote your letter. When you sign the consent form at the end, it means:

- That you have read this section.
- That you will allow the use and reporting of your health data as described above.
- You have received a form from the University Hospital. It is called the Notice of Privacy Practices form.

Clinical Trial Registry: A description of this clinical trial will be available on http://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.

COSTS TO YOU

There are no foreseeable costs to you.

ALTERNATIVES

- Your alternative to being in this study is to simply not participate.

IN CASE OF INJURY

If you are injured as a result of being in this study, please contact Dr. Konstantinos Spaniolas at telephone # 631-444-7298. The services of Stony Brook University Hospital will be open to you in case of such injury.

However, you and/or your insurance company will be responsible for payment of any resulting treatment and/or hospital stay.

YOUR RIGHTS AS A RESEARCH SUBJECT

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason, and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will get a signed and dated copy of this consent form to keep.
- You do not lose any of your legal rights by signing this consent form.

QUESTIONS ABOUT THE STUDY OR YOUR RIGHTS AS A RESEARCH SUBJECT

- If you have any questions, concerns, or complaints about the study, you may contact [Dr. Konstantinos Spaniolas], at telephone # (631-444-7298).
- If you have any questions about your rights as a research subject or if you would like to obtain information or offer input, you may contact the Stony Brook University Research Subject Advocate, Ms. Lu-Ann Kozlowski, BSN, RN, (631) 632-9036, OR by e-mail, lu-ann.kozlowski@stonybrook.edu
- Visit Stony Brook University's Community Outreach page, http://research.stonybrook.edu/orc/community.shtml#overview-of-volunteering-in-research for more information about participating in research, frequently asked questions, and an opportunity to provide feedback, comments, or ask questions related to your experience as a research subject.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

_____	_____		
Subject Name (Printed)	Subject Signature	Date	Time

_____	_____		
Name of Person Obtaining Consent (printed)	Signature of Person Obtaining Consent	Date	Time