WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TX

This research consent form is valid only if it contains the IRB stamped date

Consent for Voluntary Participation in a research study Entitled:
"Prospective Comparison of Sleeve Gastrectomy Outcomes with Different Stapling Devices"

Principal Investigator: LTC Eric .P. Ahnfeldt, DO, MC, General Surgery, 915-742-2282

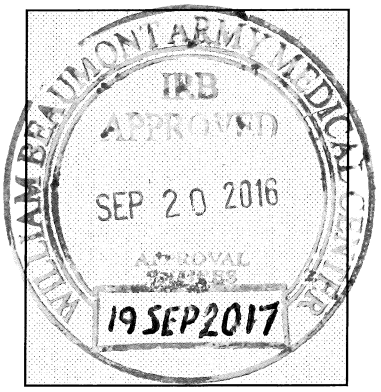
Study Site: William Beaumont Army Medical Center

1. INTRODUCTION OF THE STUDY

You are being asked to be in this research study because you have elected for a sleeve gastrectomy for bariatric surgery. Your participation is voluntary. Refusal to participate will not result in any penalty or loss of benefits to which you are otherwise entitled. That is, if you choose not to participate in this study, your surgery and the care related to your surgery will not be affected in any way. Please read the information below, and ask questions about anything you do not understand, before deciding whether to take part in the study.

2. PURPOSE OF THE STUDY

The purpose of the study is to learn about how surgical outcomes differ between two Food and Drug Administration (FDA)-approved stapling devices used for sleeve gastrectomies. Both of these stapling devices are already used for sleeve gastrectomies at WBAMC. The purpose of this study is to systematically examine differences in surgical outcomes, depending on which device is used. If you choose to participate in this study, you will be set up for surgery like any other patient who is not enrolled in this study. However, when the actual surgery takes place, we will randomly select which one of the two stapling devices (Ethicon Echilon or the Covidien iDrive) will be used. Random selection will be done by drawing an envelope with the name of one of the linear cutting and stapling devices. All surgeons are trained on both devices, but the device chosen will be based on randomization and not the surgeon preference for the sake of this study. Both staff and resident surgeons are trained on both devices, and resident surgeons involved in the procedure will be supervised by staff surgeons. During the surgery, a research resident will be observing the surgery and timing certain points, such as how long it takes to staple the stomach and how long it takes to load the stapler. All data will be recorded on a sheet with no identifiable patient information and stored on a secure computer with the patient's name and date of birth. We will be monitoring weight loss at follow-up appointments and note any unexpected outcomes after surgery. All follow-up appointments will be the same



regardless of your participation in this study.

Other studies have shown that certain practices, such as reinforcing the staple line, decrease the risk of complications after surgery, and this is our practice at William Beaumont Army Medical Center. Also, a few studies found similar outcomes between the Covidien and Ethicon devices. None, to our knowledge, have proven one device is superior to the other. We would like to test if there are differences in the two devices in an effort to ensure we are providing the best possible care to our patients.

3. PROCEDURES TO BE FOLLOWED

If you agree to be in this study, you will be asked to:

1. Show up for surgery and your follow-up appointments. You have no extra obligations as a result of this study.

By this point, you have already gone through the pre-operative counseling and work-up, so your next steps will be to see anesthesia for a pre-operative check, and they will tell you what time to show up the date of your surgery.

2. During this time, you will be randomly assigned into one of two groups by blindly drawing a card from a folder. You will also be assigned a code name that corresponds to your group. The group corresponds to the stapling device used. For example:

Group 1= Covidien (Code name C01)
Group 2= Ethicon (Code name E01)

You will not be informed in which group you have been placed. However, you can be assured that all surgeons involved in this study are trained and proficient on both devices. Both staff surgeons and resident surgeons will be involved in the study, as staff and resident surgeons are involved in these procedures in standard practice at WBAMC. All resident surgeons will be supervised by staff surgeons in accordance with standard practice at WBAMC.

3. The morning of surgery you will be given a shot of heparin to prevent blood clots, which is standard of care at our hospital. You will also receive a dose of antibiotics before the surgery starts to decrease the risk of a skin infection. A research resident will be in the room to time key portions of the surgery, as previously mentioned. The resident will record all information on a sheet of paper with your code name, so if someone else saw it, they would have no way of knowing who you are. This information will be entered into a secure, hospital computer into a sheet with your code name and a separate password-protected spreadsheet with your real name and assigned code name so we can track your progress after surgery. Only researchers on this study will have access to this document.

4. Your follow-up will be identical to anyone not involved in the study, with appointments at 3 weeks, 6 weeks, 3 months, 6 months, and annually. We will track your progress by looking at the notes from follow-up appointments in clinic for up to a year after surgery. Once all

information has been collected, analyzed, and published (without any patient information), the document with your name will be deleted within a 3-year time-frame. If you are seen by a surgeon in the emergency room, you may make mention of your involvement in the study, so we can ensure we document your visit.

4. AMOUNT OF TIME FOR YOU TO COMPLETE THIS STUDY

You will be part of this study for up to a year after your surgery. During this time you will be asked to visit the clinic 5 times, like any other post-bariatric surgery patient. Each visit will last approximately 15 minutes. None of these visits are specific to the research study. Your time commitment related to the surgery will not change if you choose to take part in this study.

5. NUMBER OF PEOPLE THAT WILL TAKE PART IN THIS STUDY

A total of up to 150 subjects are expected to take part in this study.

6. POSSIBLE RISKS OR DISCOMFORTS FROM BEING IN THIS STUDY

There are no additional discomforts expected from being in this study. All risks of surgery are expected to be equal between the two devices. These were discussed by the operative surgeon and may be found on the sleeve gastrectomy consent form that you will sign during your pre-operative appointment (medical consent form). The data collection sheet that we will maintain in the operating room will have no identifiable information, and the document that has your name is maintained on a secure hospital computer.

There is a risk of breach of confidentiality whenever your name or identifying information are collected as part of participation in a research study. Your identifying information will be protected as described above and we will use all necessary precautions to mitigate this risk.

While we do not suspect any additional risk between the two different devices, other risks about which we do not know may occur or be discovered during future studies. If we find that there was a major risk to you that was not known at the time of your participation in the study, and the risk might have some effect on your health, you will be informed.

7. POSSIBLE BENEFITS FROM BEING IN THIS STUDY

Taking part in this study may or may not affect your post-operative course. While doctors hope to find if one stapling device is better for sleeve gastrectomies than another, there is no proof yet. We do hope that information gained from this study will help us learn more about how different stapling devices affect outcomes after sleeve gastrectomy.

8. CONFIDENTIALITY/PRIVACY OF YOUR IDENTITY AND YOUR RESEARCH RECORDS

The principal investigator will keep your research records. These records may be looked at by staff from the WBAMC Department of Clinical Investigation, WBAMC Institutional Review Board (IRB), the Army Clinical Investigation Regulatory Office (CIRO), and other government agencies as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed. Complete confidentiality cannot be promised, especially to military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities. Your name will not appear in any published paper or presentation related to this study.

This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA).

9. ADDITIONAL INFORMATION ABOUT THIS STUDY

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.

10. CONDITIONS UNDER WHICH YOUR PARTICIPATION IN THIS STUDY MAY BE STOPPED WITHOUT YOUR CONSENT

Your taking part in this study may be stopped without your consent if remaining in the study might be dangerous or harmful to you. Your taking part in this study may also be stopped without your consent if the military mission requires it, or if you lose your right to receive medical care at a military hospital. If this should occur, you may discuss with your study doctor about possible non-Department of Defense (DoD) study sites for you to contact to continue in the study and, if you like, you may ask to have your study data transferred. Your participation may also be stopped if you fail to show up for follow-up appointments, get pregnant during the study period, or start smoking during the follow-up period as these actions increase chance of complications. Also, if you decide to cancel your surgery or to have a bariatric procedure other than sleeve gastrectomy, you may not participate in this study.

11. ELIGIBILITY AND PAYMENT FOR BEING IN THIS STUDY

You will not receive any payment for being in this study.

12. COMPENSATION IF INJURED AND LIMITS TO MEDICAL CARE

There are no plans for you to receive any compensation (payment) should you be injured as a direct result of being in this study. This is not a waiver or release of your legal rights or any

legal remedy available to you. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.

Should you be injured as a result of your participation in this study, you will be given medical care for that injury at no cost to you. Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for TRICARE coverage and care at military hospitals and clinics). Necessary medical care does not include in-home care or nursing home care. If you need to be hospitalized, you may have to pay the normal fees for subsistence (hospital meals), as per standard regulations.

If at any time you believe you have suffered an injury or illness as a result of participating in this research project, you should contact the Department of Clinical Investigation, WBAMC Army Medical Center at 915-742-2485.

13. COSTS THAT MAY RESULT FROM TAKING PART IN THIS STUDY

There is no charge to you for taking part in this study.

14. IF YOU DECIDE TO STOP TAKING PART IN THIS STUDY AND INSTRUCTIONS FOR STOPPING EARLY

You have the right to withdraw from this study at any time. If you decide to stop taking part in this study, you should tell the principal investigator as soon as possible; by leaving this study at any time, you in no way risk losing your right to medical care. Some testing or period of observation by the investigators may be recommended in order for you to safely stop taking part in this study.

15. STEPS TAKEN BEFORE AND DURING THIS STUDY TO PROTECT YOU

If you are pregnant, you cannot take part in this study, since you do not qualify for surgery. Females of childbearing age must take a urine or blood pregnancy test before surgery. If this test is positive, you are not eligible for surgery and may not take part in this study. If you are a female, you should avoid becoming pregnant for at least 2 years after surgery. Pregnancy within this time after surgery may be a risk to an unborn baby and yourself.

You will be monitored in the hospital at least overnight, which is standard for this procedure. All post-operative care will be identical to that for patients not enrolled in this study.

16. OTHER PROCEDURES OR TREATMENTS THAT YOU COULD CHOOSE

Your doctor can provide you with information about obesity and the benefits and risks of the different treatments available. You are encouraged to discuss this with your doctor.

Other treatments for your obesity include, but are not limited to, lifestyle intervention, band placement, roux-en-y gastric bypass, and duodenal switch. You may also choose not to have any treatment now. Your doctor can provide you with information about obesity and the benefits and risks of the different treatments available. You are encouraged to discuss these treatment choices with your doctor.

17. IMPORTANT NEW FINDINGS THAT MAY AFFECT YOUR WILLINGNESS TO STAY IN THE STUDY

If we learn new information during the study that could affect your decision to remain in this study, we will tell you this information. For example, if another study is published that has strong evidence to suggest that one stapling device is safer than another, the study will be stopped. The results of the research will be provided to you if you so desire.

18. YOUR RIGHTS IF YOU TAKE PART IN THIS STUDY

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care.

19. AUTHORIZATION FOR RESEARCH USE OF PROTECTED HEALTH INFORMATION

The Federal Health Insurance Portability and Accountability Act (**HIPAA**) includes a Privacy Rule that gives special safeguards to Protected Health Information (**PHI**) that is identifiable, in other words, can be directly linked to you (for example, by your name, Social Security Number, birth date, etc.). We are required to advise you how your PHI will be used.

(1). What information will be collected?

For this research study, we will be collecting information about time taken to create sleeve and reload staple cartridges, any bleeding or unexpected outcomes noted during the case, post-operative complications, and weight loss over time. We will access and record your name, date of surgery and follow up, and social security number for research purposes. This information will be used to access data from your medical record.

(2). Who may use your PHI within the Military Healthcare System?

The members of the research team will have access to your health information in order to find out if you qualify to participate in this study, to monitor your progress, and to analyze the research data. Additionally, your PHI may be made available to health oversight groups such as the WBAMC Department of Clinical Investigation and the WBAMC Institutional Review Board.

(3). What persons outside of the Military Healthcare System who are under the HIPAA requirements will receive your PHI?

Nobody outside the Military Healthcare System will have access to your PHI

(4). What is the purpose for using or disclosing your PHI?

The members of the research team need to use your PHI in order to analyze the information to find out whether the stapling devices we are testing are different from each other and to monitor your safety. Without using your PHI, we would be unable to track your progress after surgery.

(5). How long will the researchers keep your PHI?

The research team in the General Surgery Service will keep the research data for up to three years after the end of the study. Then all the information will be destroyed. The master code (which includes the information that could directly identify you, such as your name and social security number) will be destroyed as soon as all data collection is completed. However, the consent form and HIPAA authorization will be kept for up to six years after the conclusion of the study.

(6). Can you review your own research information?

You will not be able to look at your research information until the study has ended.

(7). Can you cancel this Authorization?

Yes. You can cancel your authorization at any time. If you cancel this Authorization, however, you will no longer be included in the research study, but you will still undergo surgery as originally planned.

However, the information that has already been collected will be kept by the research team to assure patient safety.

If you want to cancel your Authorization, please contact the Principal Investigator in writing.

(8). What will happen if you decide not to grant this Authorization?

If you decide not to grant this Authorization, you will not be able to participate in this research study. Refusal to grant this Authorization will not result in any loss of your medical benefits.

(9). Can your PHI be disclosed to parties not included in this Authorization who are not under the HIPAA requirements?

There is a potential that your research information will be shared with another party not listed in this Authorization in order to meet legal or regulatory requirements. Examples of persons who may access your PHI include representatives of the Army Clinical Investigation Regulatory Office, the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP), and the DHHS Office for Civil Rights. This disclosure is unlikely to occur, but in that case, your health information would no longer be protected by the HIPAA Privacy Rule.

(10). Who should you contact if you have any complaints?

If you believe your privacy rights have been violated, you may file a written complaint with the WBAMC HIPAA Officer, 5005 N. Piedras Street El Paso, TX 79920. Telephone: 915-742-2198.

Your signature at the end of this document acknowledges that you authorize WBAMC personnel to use and disclose your Protected Health Information (PHI) collected about you for research purposes as described above.

22. CONTACTS FOR QUESTIONS ABOUT THE STUDY

If you have questions about the study, or if you think you have a study-related injury, you should contact the Principal Investigator, LTC Eric P. Ahnfeldt, DO, MC, at 915-742-2282. For questions about your rights as a research participant, contact the WBAMC Department of Clinical Investigation at 915-742-2485, or the WBAMC Staff Judge Advocate Office, telephone 915-742-2131.

A copy of this signed consent form will be provided to you.

SIGNATURE OF RESEARCH SUBJECT

You have read (or someone has read to you) the information in this consent form. You have been given a chance to ask questions and all of your questions have been answered to your satisfaction.

BY SIGNING THIS CONSENT FORM, YOU FREELY AGREE TO TAKE PART IN THE RESEARCH IT DESCRIBES.

_____ _____

Subject's Signature Date

_____

Subject's Printed Name

SIGNATURE OF INVESTIGATOR / PERSON CONDUCTING CONSENT

You have explained the research to the volunteer, and answered all of his/her questions. You

believe that the volunteer subject understands the information described in this document and freely consents to participate.

Investigator's/Person Conducting Consent Signature Date (must be same as the subject's)

Investigator's/Person Conducting Consent Printed Name