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have been asked to read carefully all of the
(name of patient or substitute decision-maker)
nformation contained in this consent form and to consent to the procedure described below on behalf of . I have been told that I should ask questions
(name of patient)
about anything that I do not understand. (If the decision-maker signing this form is not the patient, references to 'I," "my" or "me" should be read as if referring to "the patient," when applicable.)
understand that the information about the procedure described in this consent form, in addition to discussions with my physicians and any other written or visual materials they may provide, is intended to help me make an informed decision whether to voluntarily undergo the treatment.
understand that after being examined, treated, and having various studies reviewed, I have been diagnosed as being severely overweight with a height of, weight of and Body Mass Index of I also have the following medical conditions
My physician(s) have explained to me that many scientific studies show that severe overweight increases the risk of loss of health and shortened life expectancy due to various diseases including: respiratory disease, high blood pressure, heart disease, high cholesterol, stroke, diabetes, clotting problems, digestive diseases and cancer.
understand that my physician(s) have recommended that I undergo a surgical procedure known as a Roux-en-Y Gastric Bypass to decrease my appetite, limit my food and fluid intake and lose weight.

Surgery. I will be put to sleep under general anesthesia. The type of anesthesia and the risks of anesthesia will be explained to me by a representative of the Anesthesia Department. Following the induction of anesthesia I may be given an antibiotic through a tube placed in my vein(s). My abdomen will be cleaned and covered. The surgeon(s) will locate my stomach and small intestines laparoscopically [using an optical instrument (laparoscope)] through different tubes that are placed in my body or by making a larger incision on my abdomen through which the stomach and small intestines can be seen and the stomach bypassed. My physician(s) will decide the manner in which the surgery is performed (with or without the use of a laparoscope) based on my condition, anatomy or other factors. However, I understand that even if my physicians believe they can perform the surgery using a laparoscope, they may later decide to perform or change to an open Rouxen-Y Gastric Bypass due to actual conditions observed or encountered prior to or during the surgery. My stomach will be stapled and divided or partitioned so that only a small section (able to hold 1 to 2 Tablespoons) will remain attached to my esophagus (food tube). The physician(s) will then divide my small intestine a short distance from where it joins the stomach. The shorter segment leaving the stomach will be stapled to the small portion of stomach.

<u>Post-Surgical Recovery, Care and Conditions</u>. After the surgery, I will most probably have pain. I may be given pain medications, antibiotics or other drugs as needed. I understand that it is important for my physician(s) to know all drugs that I am currently taking in order to avoid any unwanted and harmful drug interactions and I agree that prior to the surgery I will inform my physicians about all medications, drugs, herbs and supplements I am taking.

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My physician(s) will determine when I can be discharged from the hospital. I understand that I may have some restrictions and limitations after the surgery. I acknowledge that these restrictions and limitations have been thoroughly discussed with me including the dietary restrictions and nutritional supplements. I understand that these dietary restrictions are necessary to prevent pressure on the surgery and avoid vomiting in order to not strain the surgery until it is well healed. I agree to follow the dietary plan. I understand the weight loss benefits I can expect from the surgery at least partly depend on how well I participate in and continue the diet restrictions. Weight loss may not occur or may be temporary.

I understand that I will most likely develop scar tissue at the site of the incision.

Since vitamin and mineral deficiencies can occur after this surgery women of childbearing age should consult with their physician(s) regarding birth control and the timing of pregnancy.

The lower (distal) stomach may harbor conditions such as, ulcers, bleeding, and cancer that may be difficult to detect and there may be a delay in diagnosis because of the separation of the lower (distal) stomach from the food stream. These conditions as well as common bile duct diseases will be more difficult to manage and may require additional surgery.

<u>Risks of Surgery</u>. I understand that there are inherent risks in the performance of the recommended procedure and that my obesity may increase these risks. The risks include, but are not limited to:

- 1. Injury to the spleen. If my physician(s) recognize an injury to the spleen during surgery they may determine the spleen needs to be removed. (The spleen helps to prevent bacterial infections, most commonly pneumonia. Getting vaccinated can usually prevent these infections. Infections can also be treated with antibiotics. If the infections are not treated they can cause death).
- 2. Injury to other organs and blood vessels in the abdomen.
- 3. The areas where incisions were made and stapled in the stomach and intestines can leak food, fluids and digestive juices into the abdomen and increase the risk of infection. Additional medical and/or surgical treatment may be required. Serious infection within the abdomen can lead to death.
- 4. Infection. Infection, including urinary tract infection. The incision(s) are potential sites for infection. The presence of tubes to help me breathe, to help drain fluids, tubes in my veins to provide fluids, nutrition and to monitor important body functions are other sites that can become infected resulting in pneumonia, blood infections and local infections where the tubes enter my body.
- 5. Pneumonia requiring antibiotics, oxygen, and possible ventilator (breathing machine) assistance. If prolonged breathing machine assistance is needed, a tracheostomy (opening into the windpipe) may be necessary.
- 6. Scar tissue can develop in the gastric pouch and intestinal anastomosis (site where two or more tissues or organs are surgically joined) leading to blockage and inability of food, fluids, gas or waste

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to pass and be eliminated from the body. Blockage can cause severe pain and require additional medical and/or surgical treatment.

- 7. Failure of weight loss and future weight gain.
- 8. Need for readmission and reoperation.
- 9. The surgical wounds can separate.
- 10. A hernia could occur that may require additional medical or surgical treatment.
- 11. Postoperative abdominal adhesions (scar tissue inside the abdomen) that may require further treatment including surgery.
- 12. Blockage and inability of food, fluids, gas or waste to pass and be eliminated from the body (intestinal obstruction) due to adhesions (scar tissue), lack of proper motion of the intestines and other causes. Blockage can cause severe pain and require additional medical and/or surgical treatment.
- 13. Respiratory failure (inadequate ability to breathe or exchange oxygen into the blood) that could require additional medical therapy including a ventilator (breathing machine). If prolonged breathing machine assistance is needed, a tracheostomy (opening into the windpipe) may be necessary.
- 14. Nausea and vomiting and the inability to eat certain foods may persist.
- 15. Dumping syndrome, (nausea, vomiting, diarrhea with sweating, dizziness and weakness after eating) can occur and persist.
- 16. Vitamin and mineral deficiencies requiring lifetime use of supplements.
- 17. Reflux disease (stomach contents and digestive juices flow back into my food tube).
- 18. Stomach and intestinal ulcerations may occur and require additional treatment.
- 19. Bleeding from the stomach, intestine or major vessels in the abdomen. The use of blood products is unlikely. These risks include, but are not limited to bleeding, which may require the use of blood or blood products, infection, stroke, heart attack or death. If needed, blood and/or blood products have the following general risks: reactions resulting in itching, rash, fever, headache or shock; respiratory distress (shortness of breath); kidney damage; systemic infection; exposure to blood borne viruses including hepatitis (an inflammatory disease affecting the liver) and Human Immunodeficiency Virus (HIV, the virus that causes AIDS); and death. Alternatives to transfusion include the use of devices that filter and return blood lost in surgery to me or by providing medications that boost my blood count prior to an elective procedure. Bleeding and/or severe anemia could put my life in danger or cause permanent brain damage. I understand that substitutes for blood or plasma might not work well enough. Blood and/or blood products might offer the only chance to preserve my life.

☐ I refuse the transfusion of blood and/or blood products and understand that I will be asked to sign a separate form entitled, Release from Liability for Refusal of Blood Transfusion.

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- 20. Blood clots. These clots usually develop in the legs and can break free and move through the heart to the lungs. In the lungs, they can cause serious interference with breathing, which can lead to death. Blood clots are treated with blood-thinning drugs that may need to be taken for an extended period of time
- 21. Damage to nerves from pressure or positioning of the arms, legs or back during the surgery. Nerve damage can cause numbness, weakness, paralysis and/or pain. In most cases these symptoms are temporary, but in rare cases they can last for extended periods or even become permanent.
- 22. Burns caused by use of electrical equipment that may be needed to stop bleeding or by other equipment.
- 23. As with all surgeries, there is a risk of heart attack, irregular heartbeats, stroke and death, even in healthy patients.

24	Other risks, if any:	
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<u>Alternatives</u>. I understand that I have the choice <u>NOT</u> to undergo the recommended procedure or any procedure. I acknowledge that my physician(s) have discussed other alternative procedures or treatment(s) for my particular condition, if any. These alternatives may include: vertical banded gastoplasty, silastic ring gastroplasty and medical treatment with supervised dieting.

<u>Teaching Facility</u>: I understand that the facility is a teaching facility. The health care team may include residents, fellows, students, and skilled healthcare professionals. These team members may perform all or parts of my procedure under the supervision and guidance of my physician(s). I understand my physician(s) will perform or be present for the key portions of the surgery. Representatives of medical device companies may be present to provide devices, and observe and advise on their use. Who will participate and in what manner will be decided at the time of the procedure and will depend on the availability of individuals with the necessary expertise and on my medical condition.

I understand that the physician(s) or others may choose to photograph, televise, film or otherwise record all or any portion of my procedure for medical, scientific or educational purposes. I consent to the photographing, televising, filming or other forms of recording of the procedure(s) to be performed, including appropriate portions of my body, body functions or sounds, provided my identity is not revealed. I understand and agree that 1) any photographs, films, or other audio or visual recordings created will be the sole property of the facility: and 2) the facility or any appropriate staff member may edit, preserve, or destroy all or any part of the photographs, films, or other audio or visual recordings. Such recordings are not part of the medical record and I understand I cannot obtain a copy.

I authorize the disposal or retention, preservation, testing, or use for scientific, educational or other purposes of all or any portion of specimens, tissues, body parts, or other things, including prostheses and medical/surgical appliances, that may be removed from my body.

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I understand that if any medical device, as defined by federal regulations, is implanted in a patient's body, the facility is required by law to report to the manufacturer the name, address and social security number of the patient and the description and identity of the device.

MY SIGNATURE BELOW ACKNOWLEDGES THAT:

- 1. I have read (or had read to me), understand and agree to the statements set forth in this consent form.
- 2. A physician or physician's representative has explained to me all information referred to in this consent form. I have had an opportunity to ask questions and my questions have been answered to my satisfaction.
- 3. All blanks or statements requiring completion were filled in before I signed.
- 4. No guarantees or assurances concerning the results of the procedure(s) have been made.
- 5. I am signing this consent voluntarily. I am not signing due to any, coercion or other influence.
- 6. I understand that I can withdraw my consent at any time prior to the procedure.
- 7. I hereby consent and authorize Dr. _______ (my physician(s)) and/or those associates, assistants and other health care providers designated by my physician(s) to perform Roux-en-Y Gastric Bypass surgery. I understand that during the course of the surgery, conditions may become apparent that require my physicians or their designees to take steps or perform additional procedures that they believe are medically necessary to achieve the desired benefits or for my well-being, including but not limited to, the administration of blood and/or blood products and removal of my spleen (splenectomy). I authorize and request my physician(s) or their designees to perform whatever medical acts or additional procedures they, in the exercise of their sole professional judgment, deem reasonable and necessary, and I waive any obligation on their part to stop or delay the continuation of my surgery in order to obtain additional consent.

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Witness		Signature of patient or person authorized to consent for patient
Date	Time	Relationship to patient if signer is not patient
-	o the patient signing above surance as to the results that	all of the information contained in this consent form. I have given at may be obtained.