Support Person's Consent Form:

The purpose of this legal document is to confirm in the presence of witnesses that you are acting as the “Support Person” for:

_____________________________________________________________________________________________________________________

Name of person you are supporting

Relation to Patient: [ ] Spouse, [ ] Family, [ ] Other Explain: _____________________________________________________________

You are asked to please read this document very carefully!

As you read each paragraph, you are encouraged to discuss any questions about it with the patient or the surgeon.

If you agree with everything in each paragraph as you read it you are asked to:

1. Write your initials next to each paragraph
2. Check the Box next to each paragraph
3. Write at least two sentences or more describing the paragraph and showing your understanding of what you have read.

Explanation of Form Process (Your Initials and Re-Writing What You Read)

As you read this form you are asked to carefully consider the issues that are addressed in each paragraph. As a demonstration that you have read and agree with each issue you will be asked to place your initials next to the paragraph(s) that you have just read and then to rewrite the issue addressed in the paragraph(s) that you just read showing that you agree and understand the issue addressed.

Preoperative Information and Education

As the support patient for ___________________________________________ do you agree and affirm that:

   (Name of Patient)

The patient has been given extensive preoperative education and information about obesity, the risks of obesity and the risks and possible benefits of the surgical procedures in general and the Mini-Gastric Bypass in particular. The patient understands that this consent form is designed to provide a written confirmation of these discussions and educational process with Dr. Rutledge and the Centers for Excellence in Laparoscopic Obesity Surgery support staff.

The patient understands the purpose of this long document is intended to make sure that he or she has thought over the decision to have surgery. As the patient’s support person, I confirm that the patient, the patient’s family, the patient’s doctor and I have extensively reviewed the decision to proceed with this weight loss surgery.

This document is a written record of the patient’s efforts to be well informed about the decision to proceed with operation. I can confirm that the patient wishes is to consent to go forward with the proposed Mini-Gastric Bypass procedure.

In Plain English: I can vouch for the fact that the Patient is very well informed about the risks and benefits of surgery.

If you agree that, everything in the above paragraph is correct, check Yes Here: †

Initial the paragraph above

Write a Description of the Previous Paragraph and Comments (More than two sentences): _____________________________

__________________________________________________________________________________________________________________________

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__________________________________________________________________________________________________________________________
The patient's Condition/Diagnosis:
I recognize that the patient is overweight. I understand that obesity has been shown to be dangerous, unhealthy and increase the patient’s risk of death from a variety of medical illnesses. I affirm that I understand that some scientific studies conclude that obesity places individuals at increased risk of disability, respiratory disease, high blood pressure, heart disease, high cholesterol, stroke, diabetes, arthritis, clotting problems, cancer as well as other serious and less serious medical illnesses and even death.
I clearly and completely understand these issues having been aware of the patient’s own experience, discussions with the patient’s family, discussions with the patient’s doctor and from the very extensive reading and discussions with patients of CELOS and Dr. Rutledge. From this careful and calculated investigation, I believe strongly that the patient should be considered for surgery to help the patient lose weight.

In Plain English: Obesity may have serious consequences and the patient is choosing the operation in hopes of the benefits of avoiding these consequences.

If you agree that everything in the above paragraph is correct check Yes Here: ♦
Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than two sentences): __________________________

Proposed Procedure:
As the patient's support person I know the patient is fully aware that the procedure that Dr. Rutledge has recommended for the treatment the his or her obesity is the Mini-Gastric Bypass. Dr. Rutledge, with the help and assistance of the staff of The Centers for Excellence of Laparoscopic Obesity Surgery, the patient’s doctor, the patient’s family and many patients that have undergone Mini-Gastric Bypass have provided the patient with a detailed explanation of the medical history of the development of the surgical treatment of obesity, gastric surgery as a treatment of obesity, the development of laparoscopic (minimally invasive) surgery and the Mini-Gastric Bypass. The patient has been provided with drawings, photographs, written and verbal descriptions of the operation and other alternative surgeries including Open Roux-en-Y Gastric Bypass, Laparoscopic Roux-en-Y Gastric Bypass, Slapstick Ring Vertical Gastric Bypass (Fobi Pouch), Micro pouch Gastric Bypass, Antecolic Laparoscopic Roux-en-Y Gastric Bypass, Long Limb Gastric Bypass, Biliopancreatic Diversion, Biliopancreatic Diversion with Duodenal Switch, Gastric Band, Laparoscopic Gastric Band, Laparoscopic Adjustable Gastric Band, Vertical Banded Gastroplasty, Laparoscopic Vertical Banded Gastroplasty and Others.
I agree that the patient has been required to talk with patients that have previously undergone the Mini-Gastric Bypass surgery. The patient has been very strongly encouraged to make every reasonable effort to investigate and understand the details of the operation. I believe that Dr. Rutledge and the staff of CELOS have gone beyond what many other doctors do to inform the patient of the risks and benefits of the surgery and to assist the patient in making a good decision about obesity and surgery for obesity.

In Plain English: The patient has made a major effort and understands the details and complexities of the surgery: the Mini-Gastric Bypass.

If you agree that everything in the above paragraph is correct, check Yes Here: ♦
Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than two sentences): __________________________
Controversy in Medicine/Disagreements over the Surgical Treatment of Obesity

I understand that medical care often involves major controversy. I clearly recognize that Weight Loss Surgery now is filled with controversy:
I understand that there are many different types and variations in the surgical procedures being performed for weight loss in America and around the world at this time. I know that certain risks and complications can occur, but after reviewing all of the information, I feel comfortable that the patient’s family, the patient’s doctor and I agree that the Mini-Gastric Bypass is the best choice for the patient.

In Plain English: Medicine is filled with controversy. Weight loss surgery is filled with controversy and the Mini-Gastric Bypass is controversial. The patient knows that, has investigated the issues thoroughly and wants to have the Mini-Gastric Bypass surgery by Dr. Rutledge.

If you agree that everything in the above paragraph is correct check Yes Here: †
Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than two sentences): ______________
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The "Old Loop" Gastric Bypass

I know that some critics of the Mini-Gastric Bypass have compared it to the "Old Loop" Gastric Bypass. The following figures and discussion explain the differences between the Mini-Gastric Bypass, the Standard Billroth II and the "Old Loop" Gastric Bypass.

**Billroth II Gastrojejunostomy**

The Billroth II is the most commonly performed type of connection between the stomach and the small bowel. By a margin of 4 to 1, the Billroth II is preferred over the Roux-en-Y when general surgeons choose to connect the stomach to the bowel. The Billroth II is a surgical procedure used routinely in the treatment of trauma, stomach cancer and peptic ulcers. Every year over 16,000, Billroth II surgeries are performed in America alone. In the usual Billroth II, the esophagus and the body of the stomach are distant from the Billroth II connection. The Billroth II connects the stomach to the jejunum, the upper-middle portion of the small intestine. Like the Mini-Gastric Bypass, the standard Billroth II places the connection between the stomach and the small bowel low on the stomach at the junction between the body and the antrum of the stomach. The lower part of the stomach that is often removed in the usual Billroth II surgery.

Do you agree that the patient understands the Mini-Gastric Bypass is a form of gastric bypass that uses the Billroth II type of connection. The patient knows that some surgeons and other doctors do not like the Billroth II type of connection. The patient is aware of this and wants to go ahead. The patient has weighed the risks and benefits of the surgical techniques used in the MGB and favor the Billroth II type connection used in the MGB.

In Plain English: The patient knows that the Billroth II type of connection between the stomach and the bowel is a standard part of surgery and is used all the time today in the US and around the world. It is a very good, but not perfect surgical procedure.

If you agree that, everything in the above paragraph is correct, check Yes Here: †
Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than two sentences): ______________
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___________________________________________________________________________________
### The "Old Loop" Billroth II Gastrojejunostomy

Do you know and agree that the patient is well aware that there was an "Old Loop” Gastric Bypass which included a small, high stomach pouch that was placed high up on the stomach next to the esophagus. The loop that carries bile was placed close to the esophagus and this led to the associated problems with esophagitis that occurred in some surgeon’s experience with the “old loop” type gastric bypass. This configuration is in many ways much like the common general surgical procedure called a total gastrectomy. It is widely agreed that a total gastrectomy is not a good choice for a Billroth II reconstruction. This “old loop” is different from the Mini-Gastric Bypass. The “Old Loop” created a stomach pouch that was also based upon the outside edge of the stomach. This kind of pouch commonly stretches leading to failure of weight loss.

The patient is aware that there are many surgeons and doctors that feel that the “old loop” gastric bypass and the Mini-Gastric Bypass are similar and since the Old Loop did not work then the Mini-Gastric Bypass will also do poorly. The patient has investigated the Mini-Gastric Bypass in detail, I too know the difference between the old loop and the MGB and know that the patient wants to go ahead and have the MGB.”

In plain English: The Billroth II can be misused. The "Old Loop" gastric bypass placed the loop high on the stomach and this leads to bile reflux and is a poor choice.

If you agree that, everything in the above paragraph is correct, check Yes Here: †

Initial the paragraph above

Write a Description of the Previous Paragraph and Comments (More than two sentences): _______________

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### The Mini-Gastric Bypass

Do you agree that the patient understands that the Mini-Gastric Bypass does have a Billroth II type loop connection like the "old loop” bypass, but the loop in the Mini-Gastric Bypass is placed low on the stomach far away from the esophagus. This is in the same position as the loop in the standard Billroth II done for ulcers and other diseases. The Mini-Gastric Bypass creates a long narrow “gastric tube” that places the connection of the stomach and the bowel low in the stomach and keeps the stream of bile away from the esophagus. The other advantages are that the surgery is easily accessible in the event that the surgery needs to be revised.

We know that there are many surgeons and doctors that feel that the “old loop” gastric bypass and the Mini-Gastric Bypass are similar and since the Old Loop did not work well then the Mini-Gastric Bypass will also do poorly.”

In Plain English: The Mini-Gastric Bypass uses the standard Billroth II anastomosis low on the stomach and has had good results in thousands of patients.

Do you agree that the patient has investigated the Mini-Gastric Bypass in detail and knows the difference between the old loop and the MGB and the patient wants to go ahead and have the MGB.

If you agree that everything in the above paragraph is correct, check Yes Here: †

Initial the paragraph above
Previous Mini-Gastric Bypass Results:
I understand that at the present time over 5,500 total Mini-Gastric Bypass operations have been performed. I understand that the overall complication rate in the Mini-Gastric Bypass patients at this time is 5%. I know that three patients died in the first month following surgery giving an overall 30-day mortality rate of 0.05%. I know that the overall average hospital stay for Mini-Gastric Bypass patients to date has been 1.1 days. I know that the patient will probably be discharged from the hospital today or tomorrow, the day after my surgery. I am ready for this and have arranged for travel from the hospital and for care immediately postoperative when he or she leaves the hospital.

In Plain English: The Mini-Gastric Bypass uses the standard Billroth II anastomosis low on the stomach and has had good results in thousands of patients.

If you agree that everything in the above paragraph is correct, check Yes Here: †
Initial the paragraph above

Write a Description of the Previous Paragraph and Comments (More than two sentences): _______________
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Risks/Benefits of Proposed Procedure:
Just as there may be some expected benefits from the Mini-Gastric Bypass procedure proposed in the patient's case, I also understand that all medical and surgical procedures, including the Mini-Gastric Bypass involve risks. The patient has been told and I understand that the patient's obesity increases his/her risks of these problems and complications.

These risks include:

<table>
<thead>
<tr>
<th>Complications</th>
<th>Description</th>
<th>If you agree and understand check Yes Here: † And initial here:</th>
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<tbody>
<tr>
<td>Allergic Reactions</td>
<td>All kinds of allergic drug and chemical reactions are possible from my treatment, from minor reactions such as a rash to sudden overwhelming reactions that can cause death.</td>
<td>If you agree and understand check Yes Here: † And initial here:</td>
</tr>
<tr>
<td>Anesthetic Complications</td>
<td>I know and consent to the fact that general Anesthesia will be used to put me to “sleep” for the operation. I am aware that the anesthesia has major and minor risks that can be associated with a variety of different complications up to and including death.</td>
<td>If you agree and understand check Yes Here: † And initial here:</td>
</tr>
<tr>
<td>Feeling Sick, Nausea And Vomiting</td>
<td>Some operations, anesthetics and pain-relieving drugs are more likely to cause sickness (nausea) than others. Sickness can often be treated with anti-vomiting drugs (anti-emetics), but it may last from a few hours to several days.</td>
<td>If you agree and understand check Yes Here: † And initial here:</td>
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<tr>
<td>Condition</td>
<td>Description</td>
<td>Consent Requirement</td>
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<td><strong>Sore Throat</strong></td>
<td>I know I will have a tube in my airway to breathe for me during surgery and that it may give me a sore throat. The discomfort or pain lasts from a few hours to days.</td>
<td>If you agree and understand check Yes Here: † And initial here:</td>
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<tr>
<td><strong>Dizziness, Blurred Vision:</strong></td>
<td>I know that the anesthetic or loss of fluids may lower my blood pressure and make me feel faint.</td>
<td>If you agree and understand check Yes Here: † And initial here:</td>
</tr>
<tr>
<td><strong>Shivering</strong></td>
<td>This may be due to me getting cold during the surgery, to some drugs, or to stress.</td>
<td>If you agree and understand check Yes Here: † And initial here:</td>
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<tr>
<td><strong>Headache</strong></td>
<td>This may be due to the effects of the anesthetic, to the surgery, to lack of fluids, or to anxiety. More severe headaches may occur after a spinal or epidural anesthetic.</td>
<td>If you agree and understand check Yes Here: † And initial here:</td>
</tr>
<tr>
<td><strong>Bleeding</strong></td>
<td>Surgery involves incisions and cutting that can result in bleeding complications, from minor to massive, that can lead to the need for emergency surgery, transfusion or death.</td>
<td>If you agree and understand check Yes Here: † And initial here:</td>
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<tr>
<td><strong>Blood Clots</strong></td>
<td>In addition, Blood Clots, also called Deep Vein Thrombosis (DVT) and Pulmonary Embolus can sometimes occur after surgery and may cause death. I understand that I need to get out of bed the evening after surgery, move, and flex my feet and legs to try to help prevent clots from forming in my legs.</td>
<td>If you agree and understand check Yes Here: † And initial here:</td>
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<td></td>
<td>I know that surgery can result in an infection, Including wound infections, bladder infections, pneumonia, skin infections and deep abdominal infections that can sometimes lead to death.</td>
<td>If you agree and understand check Yes Here: † And initial here:</td>
</tr>
<tr>
<td>Infection</td>
<td>Leak</td>
<td>I know that after weight loss operations on the stomach the new connections can leak. The leak can allow stomach acid, bacteria and digestive enzymes to escape into the abdomen causing a <strong>severe and potentially lethal infection and or abscess</strong>. I am aware that the surgical complication most commonly related to an increased morbidity and mortality is a suture line leak. I am well aware that this is a technically demanding operation and that a leak rate of 2 to 5% for gastric bypass surgeries and 0.5% for banding procedures is frequently reported. I know that if a leak is suspected, I may need to undergo x-ray testing or emergency surgery. I am aware that emergency surgery may be needed and that multiple drains may need to be placed. I know that patients with a leak may also need to be in the intensive care unit for an extended period of time, sometime weeks or months, and <strong>I and my family clearly understand that the complication can be lethal</strong>.</td>
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<tr>
<td>Narrowing (stricture)</td>
<td>Narrowing (stricture), inflammation and/or ulceration of the connection between the stomach and the small bowel can <strong>occur after the operation this can require emergency operation, intensive care and can sometimes lead to death</strong>. To protect my new stomach from ulcers I must never again take aspirin, or aspirin like drugs such as Motrin, Ibuprofen, Naproxen, Relafen or other similar drugs.</td>
<td></td>
</tr>
<tr>
<td>Indigestion, Acid/Bile Reflux or Ulcers</td>
<td>I know that the operation can sometimes lead to severe nausea, vomiting, indigestion, abdominal pain, gastritis or ulcers. This can be severe and can last for days, weeks and possibly even longer. This is especially likely if I have had previous problems with nausea, abdominal pain or ulcers. Nausea is much more common in women than men. Women that have been treated with any type of hormone therapy (Premarin, Estrogen or Birth Control Pills) are much more likely to have nausea and vomiting after surgery. <strong>Chronic gastritis has been found in some patients years after the Billroth II surgery. Biliary duodeno-gastro-esophageal reflux can be injurious on the mucosa of the stomach and the esophagus. Bile reflux if it occurs and causes problems the operation can be revised. I know that in most cases, revision is not necessary.</strong></td>
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<tr>
<td>Ulcers</td>
<td>I know that I may develop an ulcer after surgery. I know I need to avoid ulcer causing foods, habits and medications. I know in some cases the ulcer may require surgery or reversal of my surgery. I know that <strong>Studies of patients that have had partial removal of their stomach (Post gastrectomy) can have a variety of different complications.</strong></td>
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</table>
In one study ulcers occurred in 2% of patients, Diarrhea (16%), Dumping (14%), Bilious vomiting (10%), Iron deficiency anemia (12%), B12 deficiency (14%) and Folate deficiency (32%). I understand these risks and I am ready to treat them if needed. I know that Dr. Rutledge recommends that I should not drink alcohol, take aspirin like drugs, drink coffee or soda pop as these may increase the chances of ulcers and gastritis.

<table>
<thead>
<tr>
<th>Post-gastrectomy (Stomach Removal) Problems</th>
<th>If you agree and understand check Yes Here: † And initial here:</th>
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<tr>
<td>I am fully aware that Numerous problems can follow stomach removal surgery. These “post-gastrectomy” problems may occur early after surgery or many months or years later. The early problems relate to the surgery itself. There are many late post-gastrectomy syndromes; these may be more disabling than the dyspeptic symptoms that led to the surgery in the first place. <strong>Complications of gastric surgery:</strong> Esophagus; Gastroesophageal reflux, Dysphagia Stomach; Delayed gastric emptying, Bezoars, Outlet obstruction, Stomatitis, Recurrent ulcers, Stump carcinoma, Afferent loop syndrome, Small intestine Diarrhea, Dumping syndrome, Bacterial contamination syndrome, Unmasked celiac disease, unmasked pancreatic insufficiency or unmasked lactase deficiency, weight loss and malabsorption, (Iron, Folate, Vitamin B12, Thiamine (vitamin B1), Calcium, Fats, and Anemia.) Gallbladder Cholelithiasis</td>
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<tr>
<th>Bile Reflux</th>
<th>If you agree and understand check Yes Here: † And initial here:</th>
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<tr>
<td>I know that Reflux of bile acids into the esophagus may contribute to injury of the esophageal lining. Bile is a component of digestive juices normally present in the small intestine. Bile can reflux from the small intestine into the stomach and does so normally. However, in a subset of people who have severe GERD (backwashing of acid and bile into the esophagus), including in those who have Barrett’s esophagus, there is an increase for back washing into the esophagus. Although acid plays a primary role in the development of Barrett’s esophagus, there is evidence that bile, reflux adds to the effect of acid injury to the esophagus and therefore may contribute to the development of Barrett’s esophagus and possibly esophageal adenocarcinoma (cancer).</td>
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<tr>
<th>Dumping Syndrome</th>
<th>If you agree and understand check Yes Here: † And initial here:</th>
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<tr>
<td>I know that the Dumping Syndrome (Symptoms of the dumping syndrome include cardiovascular problems with weakness, sweating, nausea, diarrhea and dizziness) can occur in some patients after gastric bypass. This can be so severe that the surgery may have to be reversed or revised.</td>
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<td><strong>Bowel Obstruction</strong></td>
<td>I know that Any abdominal operation can leave behind scar that can put the patient at risk for later bowel blockage or obstruction. <strong>The bowel can twist, obstruct and even perforate leading to serious complications and even death.</strong></td>
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<tr>
<td><strong>Laparoscopic Surgery Risks</strong></td>
<td>I know that Laparoscopic Surgery uses punctures to enter the abdomen and this can lead to abdominal organ and/or blood vessel injury, bleeding and even death.</td>
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<tr>
<td><strong>Side Effects of Drugs</strong></td>
<td>All drugs have inherent risks and complications and in some cases can cause a wide variety of side effects, reactions and in some cases including death.</td>
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<tr>
<td><strong>Loss of Bodily Function</strong></td>
<td>I know that the performance of surgery and anesthesia can stress the body’s systems leading to a variety of complications including nerve damage, stroke, heart attack, limb loss and other problems related to operation and anesthesia.</td>
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<tr>
<td><strong>Risks of Transfusion</strong></td>
<td>I know that blood and blood products are potentially dangerous with the risk of infections, including Hepatitis and Acquired Immune Deficiency Syndrome (AIDS), from the administration of blood and/or blood components. <strong>These illnesses are serious and can be fatal.</strong></td>
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<tr>
<td><strong>Hernia</strong></td>
<td>I know that cuts and incisions in the abdominal wall can lead to hernias after surgery. Hernias can lead to pain, bowel blockage, obstruction and even perforation and death in some cases. Treatment of hernias usually requires another operation.</td>
</tr>
<tr>
<td><strong>Hair Loss</strong></td>
<td>I know that many patients develop hair loss for a period after operation. When this occurs it usually starts around 3-4 months after surgery and resolves at 7-9 months after operation. I know that this usually responds to increased oral intake of protein and vitamins but it may be permanent.</td>
</tr>
<tr>
<td><strong>Vitamin and Mineral Deficiencies</strong></td>
<td>I know that after gastric bypass there is a malabsorption of some vitamins and minerals. I know patients must take vitamin and mineral supplements forever to protect themselves from these problems. I know that I also need to have yearly blood tests to measure the blood levels of these vitamins and minerals. I know that Common deficiencies that can occur after gastric bypass include iron and calcium deficiency, B12, Thiamine and Folate deficiencies. *** I know there is a risk of Wernicke's encephalopathy and other rare nerve and brain damage if I do not carefully follow these instructions. <strong>Wernicke's encephalopathy is a severe syndrome characterized by loss of short-term memory. It is linked to brain damage and is the result of inadequate intake or absorption of</strong></td>
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thiamine (Vitamin B1) coupled with continued carbohydrate ingestion.

I know that this is very important: I know that I must take vitamin and mineral supplements continuously and forever. I understand that in some cases the deficiencies are so severe that they can lead to nerve and brain damage and the operation must be reversed.

### Inadequate Weight Loss

I know that I might not lose enough weight.

**WARNING:** Remember that you might not lose weight after the operation. You might gain weight and all kinds of problems with your weight after surgery. *There are patients that will fail any type of surgery. Inadequate weight loss is a risk of all types of weight loss surgery and indeed of all types of weight loss treatment.

*I recognize that the Mini-Gastric Bypass is not by any means a perfect treatment and that one of the risks that I face is a real possibility of inadequate weight loss following my Mini-Gastric Bypass surgery.*

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### Excessive Weight Loss

I clearly understand that there is a risk that I might suffer malnutrition and lose too much weight.

I am well aware that some patients sustain excessive weight loss after weight loss operations.

I understand that excessive weight loss may require surgical revision or reversal of the bypass to prevent severe malnutrition, nausea or vitamin and mineral deficiencies or even death.

I understand that almost 1% of patients lose too much weight following weight loss surgery and need to have surgery to reverse the excessive weight loss.

As part of this agreement, I promise and agree to monitor my weight and health carefully and if excessive weight loss occurs, I will submit to early and appropriate treatment.

I hereby formally and unequivocally state that I am prepared for this possibility of malnutrition and excessive weight loss and can afford to see Dr. Rutledge and C.L.O.S. to pay for and receive the appropriate surgical treatment of a revision if necessary.

I understand and expect that the costs of surgery to reverse or revise surgery will be roughly the same as the initial surgery.

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### Complications of Pregnancy

I understand that obese pregnant women are at high risk for adverse perinatal outcome. I am also aware that there are well known risks to the patient and the baby after surgery for morbid obesity. Vitamin and
mineral deficiencies can put the newborn babies of gastric bypass mothers at risk.

No pregnancy should occur for the first one to two years after operation. **Gastric Bypass has been shown to cause multiple types of vitamin and mineral deficiencies including:** iron, B12, Folate, Thiamine, calcium and many others. Many of these deficiencies **have been shown to cause birth defects or are suspected that they could cause birth defects.** We also know that many patients who lose weight feel that they are well after surgery and forget to take their vitamins. I understand and take full responsibility to be certain not to miss any of my vitamins and obtain obstetric consultation if I decide to go ahead with pregnancy following surgery. I understand all of these risks fully and request that Dr. Rutledge proceed with surgery.

### Unplanned Pregnancy

**Warning to women using Oral Contraceptives (Birth Control Pills):** More than 80 million women worldwide take "the pill" to prevent pregnancy. Typical failure rates among pill users are as high as 12% to 20% in some surveys. Other factors have been shown to increase the risk of pill failure: smoking, diarrhea and/or vomiting drug interactions, systemic illness, psychological stress, and menstrual disturbances. Therefore, it is important to recognize that Birth Control Pills may not be an effective method of birth control after the Mini-Gastric Bypass until those factors have resolved. We have found on several occasions that in many cases the hormonal methods of birth control fail after Mini-Gastric Bypass. Couples need to plan another form of non-hormonal birth control for 6-12 months after surgery. Depo-Provera has also been associated with marked cases of nausea in post MGB patients. An unplanned pregnancy can be one of life's most difficult experiences.

If you agree and understand check Yes Here:  
And initial here: 

### Other

I know that Major abdominal surgery, including the **Mini-Gastric Bypass, is associated with a large variety of other risks and complications, both recognized and unrecognized that occur both soon after and long after the operation.**

If you agree and understand check Yes Here:  
And initial here: 

### Depression

I know that Depression and anxiety are common medical illnesses and have been found to be particularly common after weight loss operations.

If you agree and understand check Yes Here:  
And initial here: 

### Osteoporosis

I know that weight loss procedures may be associated with the development of osteoporosis and bone disease. Osteomalacia (soft bones) and secondary hyperparathyroidism can occur in obese individuals who have not undergone any kind of gastric surgery.

There is a long-standing recognition of a relationship between gastrointestinal surgery and the development of bone diseases (osteomalacia, osteitis fibrosa cystica, and osteoporosis.)

If you agree and understand check Yes Here:  
And initial here:
In one study patients who had undergone gastric bypass had lost 8% of Bone Mass Density. Similar results were found in other studies.

Gastric surgery and weight loss in morbidly obese individuals cause increased bone resorption and increased bone loss. Treatment and prevention includes calcium and vitamin D supplementation and increased physical activity.

I agree to monitor these factors lifelong by staying in touch with Dr. Rutledge and my local physician. I am aware that not following this advice can be deadly.

I agree to monitor these factors lifelong by staying in touch with Dr. Rutledge and my local physician. I am aware that not following this advice can be deadly.

Cancer

I know that cancer can occur in anyone. Many cancers are more common in obese as compared to thin patients. Overweight men have a significantly higher rate of prostate cancer. Obese women have higher risks of developing breast cancer and cancer of the uterus and ovaries. It is expected, but not certain, that with weight loss you will have an overall decrease in your risk of cancer.

The Billroth II connection used in the Mini-Gastric Bypass has been used for almost 100 years and is performed over 16,000 times a year in America to connect the stomach to the bowel.

Some studies have suggested that the Billroth II connection used in the Mini-Gastric Bypass can increase the risk of stomach cancer while others do not show this. The studies showing increase risk of stomach cancer are in Billroth II patients that had the surgery for ulcers and since ulcers can cause an increased risk of stomach cancer it may be the stomach ulcer not the Billroth II that causes some studies to show increased risk of stomach cancer after the Billroth II. Diet seems to be much more important as a cause of stomach cancer. Eating processed meats has a much greater effect on increasing stomach cancer risk that the Billroth II. Conversely fresh fruits and vegetables seem to protect against stomach cancer.

In the end no one knows what will happen in your case and if you are concerned about stomach cancer then you could choose Not have the Mini-Gastric Bypass

Death

This is a major and serious operation. It may lead to death from complications.
Risks and Complications from General Anesthesia

Do you agree that the patient understands the following: “Serious side effects of general anesthesia are well known to occur but fortunately are uncommon. This is not true in people who are unhealthy including people that are obese. Because general anesthesia affects the whole body, it is more likely to cause side effects than local or regional anesthesia. Fortunately, most side effects of general anesthesia are uncommon, minor and can be easily managed. But others can be serious or deadly. To decrease the serious and life threatening risks of anesthesia that lead to death Dr. Rutledge and the physicians and surgeons of the Centers for Excellence in Laparoscopic Obesity Surgery have chosen a very special kind of anesthetic technique that they believe improve your chances of safely recovering from surgery but may increase the chance of awareness during surgery. By your initials and comments below you agree to proceed with surgery and anesthesia with the full knowledge of the risk of awareness under this anesthesia and by your specific request that this form of anesthesia be used to improve your overall chances of safety.”

In Plain English: Anesthesia is necessary for the surgery but it is has serious risks.

If you agree that everything in the above paragraph is correct, check Yes Here: †
Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than 2 sentences): ____________

The use of Total Intravenous Anesthesia (TIVA)

Do you agree that the patient understands the use of Total Intravenous Anesthesia (TIVA) as detailed below: For the purpose of improving safety and avoiding respiratory complications of anesthesia Dr. Rutledge and the physicians and surgeons of C.E.L.O.S advocate the use of total intravenous anesthesia (TIVA). TIVA stands for Total Intravenous Anesthesia: all the medications the patient will receive will be administered through an IV catheter and will not receive anesthetic gas. Gas anesthetics, while often good choices, are deemed more dangerous than TIVA in the patients case. In summary, the patient will receive TIVA because Dr. Rutledge and the physicians and surgeons of CELOS believe it is the safest choice. The patient will have a risk of awareness during surgery (about 1-2/1,000.) The BIS electronic brain monitoring system will be used to help protect against awareness.

In Plain English: General anesthesia depresses breathing and can be deadly, TIVA depresses breathing less and is chosen by Dr. Rutledge. TIVA has a risk of waking up during surgery.

If you agree that everything in the above paragraph is correct, check Yes Here: †
Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than 2 sentences): ____________

Risks Associated with the Mini-Gastric Bypass
Do you agree that the patient understands particular risks associated with the Mini-Gastric Bypass and do you also understand that there are particular risks associated with the Mini-Gastric Bypass procedure proposed for the patient and that these risks include, but are not limited to: bleeding, leak, abscess and serious intra-abdominal infection and blood clots all of which can lead to repeated operation, admission to the intensive care unit and sometimes death. I realize that Dr. Rutledge plans to perform the operation laparoscopically, and that this approach has special risks including injury to the abdominal contents such as blood vessels, the bowel and other organs."

In Plain English: There are many serious risks of the Mini-Gastric Bypass

If you agree that everything in the above paragraph is correct, check Yes Here: †
Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than 2 sentences): __________________________

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Importance of Follow Up

Do you agree that the patient has been fully informed and understands the importance of follow up care and that the patient recognizes that an operation upon the patients stomach and upper digestive tract is a serious undertaking with known long term risks that Dr. Rutledge and The Centers for Excellence in Laparoscopic Obesity Surgery educational program have described to the patient such things as hair loss, serious vitamin and mineral deficiencies and other known and unknown problems. I believe the patient is committed to fulfilling Dr. Rutledge’s and The Centers for Excellence in Laparoscopic Obesity Surgery’s instructions for long term follow up. I promise I will make every effort to encourage the patient to follow Dr. Rutledge's directions to protect themselves from these and other problems associated with the bypass. The patient will not leave the area following surgery for 7 days after surgery and until the patient has been seen in Dr. Rutledge’s clinic and has been approved for discharge from the area.

The patient will return to Dr. Rutledge’s clinic at 1, 3 and 6 months following surgery and every year thereafter for evaluation and further education. In extraordinary circumstances in which the patient cannot reach Dr. Rutledge’s clinic he or she will be encouraged to go to his or her local medical doctor’s clinic and with his/her approval complete that follow up visit with the patients local medical doctor. In that event the patient will make certain that their medical doctor forwards copies of their clinic visit to Dr. Rutledge the Centers for Excellence in Laparoscopic Obesity Surgery. I understand and agree that Dr. Rutledge and The Centers for Excellence in Laparoscopic Obesity Surgery expects the patient to return to his clinic for follow up and it is only in unusual circumstances that the patient will miss these appointments.

I promise that I will encourage the patient to go to The Centers for Excellence in Laparoscopic Obesity Surgery’s web site at http://clos.net/ff2.htm and complete the “Patient Follow-Up Form” monthly after surgery. As part of the patients commitment to careful follow up, I promise to encourage the patient to alert The Centers for Excellence in Laparoscopic Obesity Surgery office of any changes in my address, telephone numbers, and email address or health status."

In Plain English: Follow up care after the MGB is critical (Life and Death). If I do not do the follow up with Dr. Rutledge I can die. If I kill myself by not following Dr Rutledge's advice I cannot blame Dr. Rutledge.

If you agree that everything in the above paragraph is correct, check Yes Here: †
Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than 2 sentences): __________________________

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Warning about the Risk of Seeing Other Surgeons That Perform the Roux-en-Y Surgery

Do you agree that the patient understands risk of seeing other surgeons that perform the Roux-en-Y Surgery: Recently several Roux-en-Y surgeons have written a paper saying that they have seen over 30 Mini-Gastric Bypass patients and 19 were operated on and converted to Roux-en-Y by surgery. The patient and I both know that if I see a non-MGB surgeon that I may get advice to have surgery.

In Plain English: The patient knows they can see any doctor they want to. RNY doctors prefer the RNY over the MGB. An upset stomach in an MGB patient can lead a RNY Doctor to operate. Dr Rutledge recommends to see him first for medical therapy rather than surgery.

If you agree that everything in the above paragraph is correct, check Yes Here: †

Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than 2 sentences):

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The Doctor-Patient Relationship:

Do you agree that the patient understands the importance of The Doctor-Patient Relationship:
Follow up is critical for safe long-term health after gastric bypass and for adequate maintenance of a doctor patient relationship. The follow up requirements have been described above and the patient has agreed to meet these requirements. These requirements are very important for his or her safety, are not onerous or unreasonable.
I explicitly agree to encourage the patient to comply with the clearly stated need to follow the medical advice for follow up after surgery. For example, if the patient were to sustain excess weight loss following surgery and not return to clinic to perform the agreed upon follow up, that such an action would be a breach of the doctor patient relationship and Dr. Rutledge could in no way be responsible for any untoward or bad outcomes or complications. That is to say that the patient must return to clinic for follow up if Dr. Rutledge is to have any chance of taking care of the patient. The patient has to come back to clinic for follow up for Dr. Rutledge to care for him or her. I understand that Dr. Rutledge does want to take care of the patient but that he cannot do it if the patient does not want to fulfill his or her part of the bargain. The patient needs to be responsible for follow up for Dr. Rutledge to provide medical care. This bond is the Doctor Patient relationship. The patient is willing to enter into this special bond with Dr. Rutledge and I also agree that if he or she breaks it that Dr. Rutledge cannot be held responsible for bad outcomes problems or complications.
I know and agree that in the event that the patient fails to complete his or her follow up responsibility that such actions will terminate the Doctor patient relationship. It is absolutely and unquestionably the patient's responsibility to stay in touch with the doctor after surgery. I know it is important. I know it is a life and death commitment and I am sure the patient will stay in touch and complete my follow up. In the event that the patient does not comply with the advice and directions of Dr. Rutledge then I understand that Dr. Rutledge would no longer be able to serve as the patient's physician.
I know and agree that noncompliance in meeting the agreed upon follow up requirements prevents the Doctor from providing adequate care. Dr. Rutledge has explained to the patient the critical need for continuous follow up after surgery. If he or she declines to follow the Doctor’s advice then I agree and understand such an action would sever the doctor patient relationship between Dr. Rutledge and the patient and would relieve the doctor of any responsibility he would have to me.
I agree that I am aware and agree that the physician-patient relationship depends on mutual rapport. In the event that the patient no longer follows Dr. Rutledge's advice and directions then I agree that this would terminate the relationship and any patient care responsibilities, Dr. Rutledge would be responsible for. This would mean that Dr. Rutledge would then no longer be the patient's physician.

In Plain English: Follow up care after the MGB is critical (Life and Death) If I do not do the follow up with Dr. Rutledge I can die. If I kill myself by not following Dr Rutledge's advice I cannot blame Dr. Rutledge.
Email and Telephone Calls
I know that Dr. Rutledge and the staff welcome my telephone and email communications. But I understand that a telephone call or an email is for the purposes of discussion and informational purposes only. I understand and agree here that follow up requires clinic visit so that Dr. Rutledge can see me and care for me. The information transmitted by email from Dr. Rutledge's website is not secure. Therefore confidential or sensitive information sent is solely at my discretion. I know that sending email to Dr. Rutledge does not constitute a doctor-patient relationship. I know that a doctor patient relationship can neither be created or maintained by email alone. I know that my doctor patient relationship requires following up with Dr. Rutledge in person in clinic. I know that Dr. Rutledge cannot offer specific medical advice over the Internet. I know that the information on Dr. Rutledge's website may or may not be current and may contain errors and omissions.

In Plain English: I know Dr. Rutledge cannot take care of patients over the phone or by email. I know that to get medical care from Dr. Rutledge I need to see Dr. Rutledge face-to-face, in clinic. I know Dr. Rutledge is happy to talk to patients or email people for informational and educational purposes but, Medical care requires face to face clinic visits.

If you agree that everything in the above paragraph is correct, check Yes Here: †
Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than 2 sentences): _______________
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Unexpected Outcomes:
Do you agree that the patient understands Unexpected Outcomes:
I understand that the practice of medicine and surgery is not an exact science and I acknowledge that no guarantee has been made about the results that may be obtained from this procedure. I am aware that in the practice of medicine, other unexpected problems, risks or complications not discussed may occur. I also understand that during the course of the proposed procedure unforeseen conditions may be revealed requiring the performance of additional procedures. I further acknowledge that no guarantees or promises have been made to the patient concerning the results of any procedure or treatment.

In Plain English: OK I know Dr. Rutledge has done all that is reasonable to educate the patient about the risks of the MGB surgery (over 17 pages on this alone) but no one can see the future and other bad things could happen.

If you agree that everything in the above paragraph is correct, check Yes Here: †
Initial the paragraph above
Write a Description of the Previous Paragraph and Comments (More than 2 sentences): _______________
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**Danger of Leaving the Area:**

Do you agree that the patient understands Danger of Leaving the Area:

I recognize the serious nature of this Mini-Gastric Bypass surgery. I am well informed about the risk and potential for unforeseen complications and even death. I am aware that the patient needs to stay in the area near the hospital to allow Dr. Rutledge to be able to diagnose and treat any unexpected problems or complications. I therefore confirm that I am aware that the patient must stay in the area for at least 7 days so that he or she can be available for treatment and appropriate care. I recognize that other procedures might need to be performed and I confirm that I will encourage the patient to remain in daily contact with Dr. Rutledge and The Centers for Excellence in Laparoscopic Obesity Surgery for the first 2 weeks after my surgery.

**In Plain English:** Follow up care after the MGB is critical (Life and Death). If I do not do the follow up with Dr. Rutledge I can die. If I kill myself by not following Dr Rutledge's advice I cannot blame Dr. Rutledge.

If you agree that everything in the above paragraph is correct, check Yes Here: †

Initial the paragraph above

Write a Description of the Previous Paragraph and Comments (More than 2 sentences): 

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**Support of Patient's Consent to Procedure and Treatment:**

Having read this form and talked with the patient, my signature below acknowledges that I agree that the patient is voluntarily giving authorization and consent to the performance of the Mini-Gastric Bypass procedure described above (including the administration of blood and disposal of tissue) by Dr. Rutledge, assisted by hospital personnel and other trained persons as well as the presence of observers.

If you agree that everything in the above paragraph is correct, check Yes Here: †

Initial the paragraph above

Write a Description of the Previous Paragraph and Comments (More than 2 sentences): 

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Support Person of Patient Signature:

___________________________________________ Date:

Parent or other person authorized to sign for patient:

___________________________________________ Date:

Witness:

___________________________________________ Date:
(Robert Rutledge, M.D.)