Patient Initial ___

Maryland Bariatric & Laparoscopic Surgeons
Dr Andrew Averbach & Dr Isam Hamdallah
700 Geipe Road, Suite 274
Catonsville, MD,21228
Tel 667 234 8725
Fax 667 234 8726

Informed Consent for Laparoscopic Roux-en-Y Gastric Bypass

Patient name
_____

Please read this form carefully and ask about anything you may not understand.

I consent to have a **laparoscopic Roux-en-Y Gastric Bypass** for the purpose of weight loss. I met my attending surgeon in the office during my initial consultation. My attending surgeon will perform the procedure, direct my care during the operation, and may be assisted by other physicians, fellows and/or residents under his or her supervision.

As has been explained to me, obesity is associated with early death and significant medical problems such as hypertension, diabetes, obstructive sleep apnea, high cholesterol, infertility, cancer, gastroesophageal reflux, arthritis, chronic headaches, gout, venous stasis disease, liver disease and heart failure, among other problems.

My attending surgeon has explained to me that laparoscopic Roux-en-Y Gastric Bypass can improve or cause remission of many medical problems such as hypertension, diabetes, obstructive sleep apnea, high cholesterol, infertility, cancer, gastroesophageal reflux, arthritis, chronic headaches, venous stasis disease, liver disease and heart failure. I understand there are no specific guarantees that any one of these conditions will improve or resolve in any given patient as a result of the surgical procedure.

My attending surgeon has discussed with me the alternatives to laparoscopic Roux-en-Y Gastric Bypass surgery, which include non-surgical options. The opportunity to discuss other surgical options such as implantation of a laparoscopic adjustable gastric band has been made available to me. I have advised my surgeon that I have attempted non-surgical weight loss programs without success.

I understand the anatomy of the laparoscopic Roux-en-Y Gastric Bypass procedure and have been shown illustrations of the procedure.

I have been given the opportunity to discuss alternative methods for weight loss. This includes diet and exercise as well as other surgical methods. I believe that the laparoscopic Roux-en-Y Gastric Bypass procedure offers the best balance between risks and benefits for me.

I understand the incidence of complications may be dependent on my particular medical history as well as my surgeon's level of training and experience. I have discussed these issues specifically with my surgeon.

I understand that the risks of the laparoscopic Roux-en-Y Gastric Bypass include, but are not limited to the following:

Intra-operative and/or Immediate Post-operative Risks:

Death: The mortality rate of the laparoscopic Roux-en-Y Gastric Bypass nationwide is 0.1% to 2%.
Significant Bleeding: Bleeding may occur unexpectedly in the operating room. Bleeding may also occur post-operatively in the days after the operation. This bleeding may be through the intestinal tract at the anastomosis and result in the passage of blood in the stool. Bleeding may also be unseen inside the abdomen and be diagnosed

through other means. A transfusion may be necessary in some circumstances. Re-operation to stop bleeding may be necessary.

Anastomotic Leak: A leak is when the connection between the stomach and the intestine does not heal. Serious complications can result from a leak, including, but not limited to a prolonged hospital stay, a long period of nothing to eat, prolonged antibiotic requirements, organ failure and death. The reported incidence of anastomotic leak nationwide ranges from 0.25% to 3%.

Renal Failure: Transient kidney (renal) failure occurs rarely. Irreversible kidney failure has been reported in rare cases.

Prolonged Ventilation: A prolonged stay on a ventilator (breathing machine) in the intensive care unit may occur if a patient has severe sleep apnea or after certain significant complications. A temporary tracheostomy may be necessary.

Heart Attack: Although a heart attack is possible after a laparoscopic Roux-en-Y Gastric Bypass, it is very rare. Risk factors for heart disease include increased age, diabetes, hypertension, hypercholesterolemia and a family history of heart disease.

Prolonged Hospital Stay: Unforeseen complications may result in a prolonged hospital stay. Intensive care admission may be required.

Bowel Obstruction: An obstruction can occur that would require re-operation. An obstruction can occur from a number of causes, such as bleeding, scarring, technical problems or hernia.

Deep Vein Thrombosis (DVT)/Pulmonary Embolism: Blood clots that form in the legs, and elsewhere, and break off into the lungs may cause death. Given this risk, treatments may be initiated to decrease the risk for the formation of blood clots, including the use of heparin (a medication that thins the blood), special foot and leg stockings, walking soon after surgery and medication at home after discharge from the hospital. Completely eliminating the risks of DVT (clots) altogether is not medically possibly. The risks associated with the medications used to prevent blood clots can include excessive bleeding. Any symptoms of leg swelling, chest pain or sudden shortness of breath should be immediately reported to the surgeon. Rarely, patients develop allergies to heparin, sometimes causing very severe reactions.

Other Complications that may be common: Allergic reactions, headaches, itching, medication side-effects, heartburn/reflux, bruising, gout, anesthetic complications, injury to the bowel or vessels, gas bloating, minor wound drainage, wound opening, scar formation, stroke, urinary tract infection, urinary retention, pressure sores, injury to spleen or surrounding structures, and pneumonia.

Risks Associated with an Open Procedure: If a conversion to an open procedure is required, complications include but are not limited to: wound infection, which may cause significant scarring and healing problems, prolonged wound care, and discomfort. Incisional hernias occur in approximately one-third of patients after an open Roux-en-Y Gastric Bypass. Hernias will often require an operation to repair. There is a higher chance of certain complications including lung infections, pressure ulcers and blood clots after an open operation. There would also likely be more discomfort and a longer hospital stay.

Risks in the Early Postoperative Period:

Stricture: It has been reported that connection between the stomach and the intestine, the gastrojejunostomy, can scar to the size of a pinhole. This is a relatively common complication. This scarring is diagnosed by the intolerance to solid foods after surgery. A stricture can be treated by endoscopic balloon dilation. Under sedation,

a scope (1/2-inch diameter tube with a camera) is placed through the mouth and into the stomach pouch. The stricture is then dilated with a balloon. On occasion, a dilation may be required several times. Very rarely, re-operation would be necessary.

Ulcer: An ulcer can cause pain, bleeding or result in a perforation. Ulcers are more common in patients who take medications such as aspirin, Advil®, Motrin®, Aleve®, Ibuprofen, or other drugs classified as NSAIDS. Aspirin, Celebrex® and Vioxx® can cause ulcers when used for prolonged periods of time. Also, patients who smoke tobacco are at higher risk for the development of an ulcer.

Fatigue: After any general anesthesia, fatigue is very common. Fatigue may last days, or in some circumstances, much longer.

Food Intolerance: Following laparoscopic Roux-en-Y Gastric Bypass, patients may experience an intolerance to certain food types, usually fatty greasy foods, dairy products, and/or sweets, which may cause unpleasant symptoms similar to seasickness such as sweating, nausea, diarrhea and shaking. These symptoms may last from a few minutes to an hour. This is called "dumping." Food intolerances vary from person to person. Some patients never experience any of these symptoms, or may become less sensitive over time. Rarely, a patient may have severe food intolerances that last for many months.

Late Complications:

Osteoporosis: Calcium deficiency may occur years after a laparoscopic Roux-en-Y Gastric Bypass. This is a difficult diagnosis to make until weakness of the bone has already developed.

Iron Deficiency Anemia: Since iron is not as easily absorbed after the laparoscopic Roux-en-Y Gastric Bypass, supplements are generally recommended in all patients to prevent anemia. Serious complications can occur with severe anemia. Iron stores can be measured by blood tests and should be routinely performed. Sometimes oral iron supplements are not adequate to treat anemia and intravenous iron is recommended.

B Vitamin Deficiencies: Deficiencies in Thiamine, Niacin, B12 and others have been reported. These B vitamin deficiencies are very rare. Some B vitamin deficiencies can cause irreversible neurological damage. All patients are required to take a multivitamin supplement for life after this operation. Sometimes, additional B vitamin supplements are also required. It is important to be evaluated regularly for vitamin deficiencies after surgery. Severe vomiting is a risk factor for the development of B vitamin deficiencies.

Bowel Habits: Changes in bowel habits are common. Changes may include constipation, diarrhea and excessive flatus. Food intolerances are very common and unpredictable.

Internal Hernia: Some patients may develop a twist in their intestines after laparoscopic Roux-en-Y Gastric Bypass which may cause intermittent and/or severe abdominal pain, and can in rare cases be fatal. These symptoms may occur any time after surgery.

Intestinal obstruction: Can occur secondary to adhesions or scarring, lifetime risk is 1.5-2%, if it happens might require a surgical intervention to relieve that.

Pregnancy: I understand the pregnancy should be deferred for 18 months after laparoscopic Roux-en-Y Gastric Bypass surgery because of concern for fetal and maternal health. I also understand that fertility may be substantially increased very early after surgery due to my weight loss. I understand that I am responsible for using appropriate birth control methods in this time period. Studies appear to show a decreased rate of complications of pregnancy in those patients who have had laparoscopic Roux-en-Y Gastric Bypass. There may be rare instances where complications of pregnancy may be increased secondary to having laparoscopic Roux-en-Y Gastric Bypass.

Gallbladder Problems: Significant weight loss promotes the formation of gallstones. There is an increased risk in the future of requiring removal of the gallbladder due to gallstones.

Weight Regain: Modest weight regain years after surgery is typical. Significant weight regain may occur more rarely. The causes of weight regain are complex.

Excessive Weight Loss: Excessive weight loss is uncommon and usually results from complications that require close management by the surgeon.

Psychiatric Complications: Although most people experience improvements in their mood, some will have worsening states of depression which could lead to suicide. There may be a higher incidence of marital problems after weight loss surgery. Patients taking psychiatric medications should have the dosage and effectiveness of these medications monitored carefully by their prescribing physician.

Temporary Hair Loss: Hair loss occurs in many people after a weight loss operation. Hair generally grows back. There are no proven supplements to alter hair loss.

Dumping Syndrome and associated symptoms can occur following surgery, most of the cases can be managed be dietary modifications.

Autonomic Dysfunction (causing dizziness when standing) and hypoglycemia are not uncommon symptoms after surgery and it might require revisional surgery.

Other Complications: There may be other extremely rare and significant complications that may occur, which are not well described to date.

Unlisted complications: I understand that it is impossible to list every complication possible during and after this procedure.

Possible Additional Procedures:

During the laparoscopic Roux-en-Y Gastric Bypass operation, several conditions may arise that may cause additional procedures to be performed. These include:

A liver biopsy: Many patients will have a liver biopsy performed. Bariatric patients often have some degree of liver disease. A biopsy helps determine the severity of liver disease (if present at all) and helps with post-operative management. The risks with performing a liver biopsy include a low chance of bleeding.

Removal of the gallbladder: In some patients, removal of the gallbladder may be medically necessary. Removal of the gallbladder increases the length of time of the total operation. There is a small risk of bile duct injury that can result in serious complications. Removal of the gallbladder may increase the hospital stay and increase post-operative pain. An additional port (and incision) may be necessary to perform the procedure safely.

Gastrostomy Tube: Although rare, placement of a gastrostomy tube (G-tube) may be performed. A G-tube may be placed in the excluded, lower portion of the stomach when the laparoscopic Roux-en-Y Gastric Bypass operation was much more difficult than expected, or when the procedure is a revision of a previous weight loss operation. Associated complications with a G-tube include, but are not limited to: leakage of stomach contents around the tube which can irritate the skin; persistent drainage even after removal of the G-tube (fistula); mild discomfort around the G-tube; and premature removal of the G-tube which may necessitate emergency re-operation.

Incisional Hernia repair: A hernia may have to be repaired at the time of the operation.

Esophagogastroduodenoscopy: An EGD, or upper endoscopy, is sometimes performed during the laparoscopic Roux-en-Y Gastric Bypass operation in order to visualize the stomach, the new intestinal connection or to make sure there are no other abnormalities of the intestinal tract.

Hiatal Hernia repair: If a hiatal hernia is present, this may require repair during the surgery. The associated risks with a hiatal hernia repair include, but are not limited to injury to the esophagus, dysphasia (difficulty swallowing) and hernia recurrence.

Lysis of Adhesions: In the setting of a previous operation or significant abdominal infection, scarring always results. The degree of scar tissue is unpredictable. Sometimes, depending on the location of the scar tissue, the scar tissue must be cut (called "lysis of adhesions") in order to perform the weight loss operation. There are increased risks when a lysis of adhesions is necessary, including injury to the intestines, prolonged operative times and bleeding.

Placement of a Drain: In certain circumstances, the surgeon may elect to place a temporary plastic drain. A drain is a thin plastic tube that comes out of the body into a small container to allow for the removal of fluid and the control of infection.

Risks/Possible Complications. The doctor has explained to me that there are risks and possible undesirable consequences associated with a Laparoscopic sleeve gastrectomy including, ***but not limited to***:

1 **Abscess**
2 **Adult Respiratory Distress Syndrome (ARDS)**
3 **Allergic reactions**
4 **Anesthetic complications**
5 **Atelectasis**
6 **Bleeding, blood transfusion, and associated risks**
Blood clots, including pulmonary embolus (blood clots migrating to the heart and lungs) and deep vein thrombosis (blood clots in the legs and/or arms)
7 **Bile leak**
8 **Bowel obstruction**
9 **Cardiac rhythm disturbances**
Complications in subsequent pregnancy (no pregnancy should occur within the first 18 months after surgery)
10 **Congestive heart failure**
11 **Dehiscence or evisceration**
12 **Depression**
13 **Dumping syndrome**
14 **Death.**
15 **Encephalopathy**
16 **Esophageal, pouch or small bowel motility disorders**
17 **Gout**
18 **Hernias, incisional (including the port sites for laparoscopic access) and internal**
19 **Inadequate or excessive weight loss**
20 **Infections at the surgical site, either superficial or deep including port sites for laparoscopic access. These could lead to wound breakdowns and hernia formation.**
21 **Injury to the bowels, blood vessels, bile duct, and other organs**
22 **Injury to adjacent structures, including the spleen, liver, diaphragm, pancreas and colon**
23 **Intestinal leak**
24 **Kidney failure**
25 **Kidney stones**
26 **Loss of bodily function (including from stroke, heart attack, or limb loss)**

Myocardial infarction (heart attack)
Narrowing of the connection between the stomach and small bowel
Need for and side effects of drugs
Organ failure
Perforations (leaks) of the stomach or intestine causing peritonitis, subphrenic abscess or enteroenteric or enterocutaneous fistulas
Pleural effusions (fluid around the lungs)
Pneumonia
Possible removal of the spleen
Pressure sores
Pulmonary edema (fluid in the lungs)
Serious intra-abdominal infection such as sepsis or peritonitis
Skin breakdown
Small bowel obstructions
Staple line disruption
Stoma stenosis
Stroke
Systemic Inflammatory Response Syndrome (SIRS)
Ulcer formation (marginal ulcer or in the distal stomach)
Urinary tract infections
Wound infection

a. Nutritional complications ***include but are not limited to:***

Protein malnutrition
Vitamin deficiencies, including B12, B1, B6, folate and fat soluble vitamins A,D,E,K
Mineral deficiencies, including calcium, magnesium, iron, zinc, copper, and other
Uncorrected deficiencies can lead to anemia, neuro-psychiatric disorders and nerve damage, that is, neuropathy

b. Psychiatric complications ***include but are not limited to:***

1. **Depression**
2. **Bulimia**
3. **Anorexia**
4. **Dysfunctional social problem**
5. **Alcohol dependency and recidivism**

c. Other complications ***include but are not limited to:***

Adverse outcomes my be precipitated by smoking
Constipation
Diarrhea
Bloating
Cramping
Development of gallstones
Intolerance of refined or simple sugars, dumping with nausea, sweating and weakness
Low blood sugar, especially with improper eating habits
Vomiting, inability to eat certain foods, especially with improper eating habits or poor dentition
Loose skin
Intertriginous dermatitis due to loose skin

12 **Malodorous gas, especially with improper food habits**
13 **Hair loss (alopecia)**
14 **Anemia**
15 **Bone disease**
16 **Stretching of the pouch or stoma**
17 **Low blood pressure**
18 **Cold intolerance**
19 **Fatty liver disease or non-alcoholic liver disease (NAFLD)**
20 **Progression of pre-existing NALFD or cirrhosis**
21 **Vitamin deficiencies some of which may already exist before surgery**
22 **Diminished alcohol tolerance**

d. Pregnancy complications were explained as follows:

1 **Pregnancy should be deferred for 12 to 18 months after surgery or until the weight loss is stabilized**
2 **Vitamin supplementation during the pregnancy should be continued**
3 **Extra folic acid should be taken for planned pregnancies**
4 **Obese mothers have children with a higher incidence of neural tube defects and congenital heart defects**
5 **Pregnancy should be discussed with an obstetrician**
6 **Special nutritional needs may be indicated or necessary**
7 **Secure forms of birth control should be used in the first year after surgery**
8 **Fertility may improve with weight loss**

Further, any of these risks or complications may require further surgical intervention during or after the procedure, which I expressly authorize.

I also understand that some or all of the complications listed on this form and also explained to me may exist whether the surgery is performed or not, in that gastric bypass surgery is not the only cause of these complications.

I have had the opportunity to read these materials, speak with my attending surgeon, and ask any questions. I understand that unforeseen events may occur that could result in the last minute cancellation or postponement of my surgery. I have reviewed all of the information in this consent form and related consent materials with my immediate family. I have clearly stated to my closest family members that I fully understand the risks of surgery and accept such risks. I have read, or had read to me, the contents of this consent form and related consent materials and have no further questions. I wish to proceed with laparoscopic Roux-en-Y Gastric Bypass.

_____ _____
Printed Name Date and Time

_____ _____
Patient's Signature Surgeon's Signature

_____ _____
Witness to signature only Date and Time