

Note to the patient:

Your consent form has three parts:

- 1) The general consent form for adjustable gastric banding. Please read the entire form carefully and place your initials next to each and every paragraph. Pages 2 – 9.**
- 2) A short quiz of questions related to the surgery. Answers are provided on the page following the quiz. Pages 10 – 11.**
- 3) A consent form to participate in the national database for Bariatric Surgery Centers of Excellence, called “BOLD”. Participation is not required but we encourage you to participate in this national study which requires no work on your part. If you are participating, on the first page of the “BOLD” consent form (page 12), please fill out the name of your surgeon and the facility where you will have the surgery. Pages 12 -16.**

Informed Consent

Laparoscopic (Possible Open) Adjustable Gastric Banding System

You have decided to undergo laparoscopic, possible open, **Adjustable Gastric Banding System** placement. During the last several weeks/months, as we have prepared you for your surgery, we have provided you with detailed information about the operation, as well as the other options and procedures which you have for control of your weight. You have learned about the potential benefits and risks to you in having the operation. The purpose of this **consent** is to confirm your decision, based upon knowledge and understanding of the operation. You may always change your mind about proceeding with the operation.

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

Obesity is a disease that often has multiple associated medical illnesses and is associated with a decrease in life expectancy. Some of these illnesses may be diminished with significant durable weight loss. The National Institutes of Health panel of physician experts concluded that for some of the morbidly obese, diet/exercise/medications including M.D. supervised medications/diets have a high failure rate and that bariatric surgery may be the most effective tool to achieve long term weight loss in these patients. The risk of a non-surgical approach to your obesity, therefore, is a high failure rate in significant, long-term weight loss resulting in increased risk for obesity-related medical illnesses and decreased life expectancy.

The **Adjustable Gastric Banding System** is designed to create a small reservoir at the upper end of the stomach by placing a silicone adjustable band. This is usually placed laparoscopically although the open method may be used in some rare instances. The procedure involves making several small incisions through which the surgeon inserts laparoscopic instruments to make the necessary changes and apply and secure the **Adjustable Gastric Banding System** device to the upper portion of the stomach. There is also a port attached to the **Adjustable Gastric Banding System** device that is secured to underlying tissue on the abdomen. The port can be accessed in the post-operative period by the surgical team, using a special needle, to make necessary adjustments of the inside balloon. This procedure functionally restricts the size of the stomach to about 2-oz and is considered a strictly gastric restrictive procedure although some suggest, when appropriately adjusted, it does decrease appetite as well. The difference between this and other restrictive bariatric procedures is that the restrictive effect can be adjusted, and this currently is the only bariatric procedure that can be adjusted without surgery in the post-operative period. Weight loss occurs by restricted intake – the purpose of the smaller stomach pouch is to create the sensation of fullness earlier (satiety), thereby decreasing the desire for food and limiting the volume of food one is capable of consuming at one time. There is no division or bypass of the stomach. Of note, with this limited intake, if you eat too much at one meal, you may feel discomfort and may even vomit until you learn the capacity of your “new” stomach. It generally carries the fewest complications of the current bariatric procedures.

Weight loss is more gradual than other bariatric procedures and eating high calorie liquid or soft foods can circumvent the procedure. There is no malabsorption of nutrients.

Weight loss with the **Adjustable Gastric Banding System** is reported at 35-68% of excess body weight. Health problems associated with excess weight are also usually benefited. Lastly, the **Adjustable Gastric Banding System** is reversible. There are multiple other bariatric procedures available including laparoscopic and open Roux-en-Y gastric bypass, vertical banded gastroplasty (VBG), and duodenal switch/biliopancreatic diversion. Experimental procedures such as gastric pacing are not available outside the research setting at this time.

The Roux-en-Y divided gastric bypass is the most widely accepted and common procedure performed by bariatric surgeons in the United States. Weight loss with the Roux-en-Y divided gastric bypass usually exceeds 50% of excess body weight, and many patients lose 75% or more of excess weight. Health problems associated with excess weight are also usually benefited. Roux-en-Y divided gastric bypass is designed to make a small reservoir (“pouch”) for food at the upper end of your stomach with a capacity of about 2-oz. This pouch is connected to the upper small intestine by a new small anastomosis (outlet) of about ½ inch (1.2 cm) in diameter. The ingested food thereby **bypasses** the majority of your stomach, which remains alive and undisturbed, but functional otherwise. In other words, the majority of your stomach does not have food passing through. It often is associated with a permanent decrease in appetite. The nature and purpose of this operation is to functionally limit the amount of food or liquid intake at any given time. There also may be a small component of malabsorption, at least initially. There are side effects such as “dumping” which can occur after eating sweets or fatty foods and although unpleasant, is an after effect that some find useful in reinforcing good dietary choices. The risk of gastric bypass includes complications such as a “leak” at the suture/staple line which can be serious and life-threatening. Strictures, internal hernias, and outlet ulcers are also a possibility and not commonly seen with the Adjustable Gastric Banding System.

The VBG aims to functionally restrict the size of the stomach. It is usually not adjustable and in some reports is associated with a high failure rate and reflux. For these reasons, it is out of favor with many bariatric surgeons.

The duodenal switch/biliopancreatic diversion procedures are malabsorptive procedures and may carry the highest complication rate among bariatric procedures. Weight loss occurs by lack of absorption of nutrients rather than by loss of appetite and restricted intake. These procedures can cause foul smelling diarrhea and can be complicated by anemia, protein malnutrition, liver failure, vitamin (especially fat-soluble) and mineral deficiencies.

Regardless, all available procedures are tools, which when used appropriately, may help you to lose a significant amount of weight and keep it off and have proven benefit over non-surgical weight loss. However, no surgery can offer a guarantee of significant weight loss.

For most people, weight loss is more gradual with the **Adjustable Gastric Banding System** than the gastric bypass however the weight loss for the two groups is about the same after three years in compliant patients. More than any other bariatric procedure, your chance of achieving your weight loss goals is greatest if you continue regular follow-up with our bariatric program after your surgery to monitor your progress and perform adjustments as necessary. Like any other bariatric procedure, there are ways to defeat the purpose of surgery and gain weight. It is possible to defeat the purpose of surgery by continuous drinking of high calorie soft foods or liquids and/or snacking throughout the day. In general, if you choose a balanced menu high in protein content, eat at normal times, and incorporate exercise into your daily routine, this tool will allow you to lose weight and keep it off for the long term.

Understandably, you should not be pregnant at the time of surgery. If you are a woman, you should avoid pregnancy for the first year post-operatively. Periods of rapid weight loss are not the right time to be carrying and nourishing a baby and may lead to complications of the pregnancy or with the baby. Although you may think you are infertile (unable to bear children), this is often related to the obesity and once you lose the weight, you may be more likely to get pregnant. So please use caution in the first year after surgery.

Alcohol consumption is discouraged, as it is a high calorie liquid, which can defeat the purpose of the surgery. You may also experience increased intoxication with less volume intake than prior to surgery for unclear reasons.

General risks which apply to all abdominal surgery include but are not limited to anesthesia (greater in the morbidly obese), deep venous thrombosis (“DVT”, also known as blood clots), pulmonary embolism, death, brain damage, infection, bleeding, pneumonia, cardiac events (heart attack), stroke, bowel obstruction, intra-abdominal abscess, damage to other intra-abdominal structures (bowel, solid organs, blood vessels) adhesions, wound infections (less with the laparoscopic approach), incisional hernias, internal hernias, disfiguring scars, the loss of function of body organs, chronic pain, among others.

Blood clots in the veins in the legs or pelvis (DVT's) can migrate to the lungs (pulmonary embolism) which can be fatal. Fortunately the risk of this is less than one percent. To avoid this serious complication which can occur after **any** type of surgery, we take several important measures. You will be asked to ambulate early, usually in the first few hours after surgery. We also want you to walk as much as possible prior to surgery to increase blood flow in the legs. We will have compression stockings on your legs during the surgery and until you are walking well. We will generally give you a blood thinner subcutaneously during your hospital stay. We will generally use Toradol, an anti-inflammatory with some blood thinning properties (anti-platelet), during the hospitalization.

Smoking carries with it an increased risk of clotting and we ask that you stop smoking prior to and after surgery.

Pulmonary complications such as pneumonia and atelectasis (partial collapse of the lungs) can occur after any type of surgery under general anesthetic. Once again, there are several things you can do to decrease your risk of these complications including stopping smoking, early walking after surgery, and using your incentive spirometer. The incentive spirometer is a device to help you expand your lungs in the post-operative period and you will be given one to take home after surgery. If you are a smoker, you are at increased risk of pulmonary complications. Only rarely do pulmonary complications require prolonged need for a ventilator (breathing machine).

Stay well hydrated the day prior to surgery and then nothing to eat after midnight for surgery the next day.

It is unusual that you will need a blood transfusion, as the risk of significant bleeding is less than 1%. If you require blood, you will be transfused American Red Cross Blood. The most common risks of transfusion are:

- 1) fever
- 2) transfusion reaction – an exceedingly rare instance in which you would receive the wrong blood type which can cause serious illness, possibly kidney failure
- 3) Hepatitis – a viral infection of the liver, which can rarely lead to acute liver failure or more likely, can lead to chronic infection which over time can cause cirrhosis and possibly liver failure.
- 4) HIV – a viral infection which can lead to AIDS.

Risks which apply in particular to the **Adjustable Gastric Banding System** include the above as well as the following:

1) **Slippage of the band:** This risk is about 4-7%. The stomach surrounding the band can slip up causing obstructive symptoms or reflux. It generally occurs with episodes of severe retching, especially early in the post-operative period before the band has scarred in completely. The band is sutured in place during the initial operation. If a slip occurs, it can be repaired in most instances by re-suturing it in place laparoscopically.

2) **Damage to the spleen or other organs:** The spleen lies close to the upper portion of the stomach and can be injured in up to 10% of open upper surgeries on the stomach. Fortunately, it is rare to injure the spleen during laparoscopic surgery, and the rate is under 1%. If your spleen is injured, this may require conversion to an open procedure and possibly removal of the spleen to prevent bleeding. Pancreatitis is a rare but reported complication. Liver injury rarely requires any additional treatment. Unrecognized injury rarely occurs to the stomach or intestines but can lead to peritonitis requiring more surgery, future problems or even death. If recognized, it can be repaired (usually laparoscopically) but the band placement may need to be postponed to avoid infection.

3) **Infection:** The risk of band and/or port infection is generally around 1% - 3%. The entire band/tubing/port is placed sterilely and resides completely underneath the skin. It can become infected if accessed un-sterilely, if you develop an infection in another location (urinary tract, pneumonia, etc.) that “seeds” the port/band, or if you develop an erosion (see below). Once again, this is fairly rare. Unfortunately, however, if you develop an infection, the band or port may need to be removed. It may be replaced, usually laparoscopically, at a future time once all infection has resolved.

4) **Erosion:** A rare complication reported mostly in the early studies in Europe and Australia. The risk appears to be less than 1%. Apparently the band erodes into the stomach causing a loss of restriction and weight gain. It usually does not cause significant peritonitis (intra-abdominal infection), but may require laparoscopic removal of the band/port. It may be laparoscopically replaced at a later date.

5) **Port problems:** Leaks where the port connects to the band tubing are now less common since the company re-designed the connection to rest in the abdominal cavity rather than on the muscle. Leakage from the port itself may occur from mechanical complications or needle sticks. Malpositioning of the port such as the port “flipping” may require that your port be accessed under a fluoroscopy (X-Ray) or require an additional procedure to reposition the port. If any of these occur it may result in an additional procedure which may result in extra costs to you.

6) **Death:** The mortality rate of **Adjustable Gastric Banding System** is under 0.5% and parallels the death rate of procedures such as elective laparoscopic cholecystectomy in similar patients. **Although very safe, Adjustable Gastric Banding System placement is still major surgery and you and your family members should realize that complications of this procedure could be fatal. Only you can make the final determination to decide if you think the benefits of surgery outweigh the risks of surgery.**

7) **Psychological factors** including post-operative depression (as a result of weight loss, required diet change, complications of surgery) or possibly a reaction to the stress of surgery are possible: Family members may also experience these. Studies have shown that most patients have an improvement in depressive symptoms after surgery, and it is much more likely that you will be very pleased with this life-changing procedure rather than the opposite.

8) **Gallstones:** There may be an increased risk of developing gallstones after **Adjustable Gastric Banding System**. The exact mechanism is unknown, but gallstones do develop more often during periods of rapid weight loss.

9) **Extreme weight loss:** Fortunately this is very rare. Most people will stabilize at a weight that is healthy for them.

10) **Failure to lose weight:** Although almost everyone will lose weight early on, it is possible to defeat the purpose of this surgery as discussed above.

11) **Gas pains or excessive flatulence** can occur and are usually controlled with simethicone, sometimes Levsin: In general, the Adjustable Gastric Banding System should not affect your bowel habits to any significant degree.

12) **Large folds of skin:** This is always a possibility with significant weight loss. There is no reliable way to determine before surgery if this will occur after surgery. Plastic surgeries are available to correct this problem if desired.

13) It is also possible to get **food stuck** at the level of the band if you eat too large a piece of food, don't chew well, or advance your diet more rapidly than advised: This may require an endoscopy to clear the trapped food.

Other complications may possibly occur with less frequency. Not all side effects or hazards of the operation may be known, and the result of surgery cannot be guaranteed. Once again, every effort is made to prevent problems, and you need to understand and accept that they may still occur.

Although over 250,000 **adjustable gastric band** procedures have been performed worldwide since 1993, and the **LapBand** received FDA approval in the United States in June 2001, there may be long term problems not known at this time.

Re-operation may be needed, at some future time, to correct problems, which might occur. The adjustable gastric band is reversible, usually laparoscopically, although there is seldom any practical reason to consider reversal or laparoscopic conversion to bypass. Certainly advances in medical treatment of obesity may occur in the future that would possibly make reversal an appropriate option.

Best results occur with regular follow-up, attendance in the support groups, exercise, adjustments to the band, and appropriate eating habits.

A common misperception that we see are patients who want to rush their weight loss and think this can be achieved by having the gastric band very tight. This actually leads to weight gain in most patients, because the ability to eat normal foods is lost and results in nausea and vomiting. Therefore, in order to eat, patients turn to soft, high calorie foods. **Even worse, having your gastric band too tight increases your risk of complications of the Band such as slip, erosion, esophageal dilatation and pouch enlargement, which could result in the need for further surgery or even removal of the band.** Please don't fall into this trap and don't try and rush the process!

Paying out of pocket “cash pay” or high deductibles. Several insurance companies either exclude coverage for Bariatric surgery, have high deductibles, have unreasonably strict guidelines, or only approve certain procedures. In any event, some patients will pay for the entire procedure themselves or pay a large co-pay/deductible. The money spent is often tax deductible (consult your tax attorney or accountant) and there are some financing options available. **Please be aware that if you have an exclusion and are paying entirely out of pocket for your procedure (NOT those with high deductibles or co-pays generally), payment does not generally cover potential surgical complications. Your insurance may not cover fees incurred by the hospital, lab, radiology, anesthesia, etc. We may bill your**

insurance company for additional procedures done unrelated to the surgery itself (examples: lysis of adhesions, repair of hiatal hernia, repair of abdominal wall hernia, removal of the gallbladder or other organ, etc.). Significant complications often require additional hospital stay, testing, medications, additional procedures, etc. that will be the responsibility of the patient.

Surgical treatment is a participatory alternative (elective) and should not be considered a cure-all or quick fix. It does not affect the underlying causes of obesity whether genetic, environmental, psychological, or hormonal. However, in most cases, surgery is effective in achieving durable weight loss.

You have the right to a second opinion.

You are encouraged to have attended an educational seminar.

You have been given the opportunity to attend support groups and to discuss the results of this procedure with other patients.

Your family and friends are encouraged to participate in the educational process, as their support is important and beneficial following surgery.

You give the **consent** to the existing possibility that once the procedure has been begun laparoscopically; it may be necessary to convert to an open procedure. This will be decided by your surgeon and performed with your best interest in mind. Any other encountered pathology (abnormalities) seen at the time of surgery will be addressed as indicated in the surgeon's best judgment. In the rare event that the adjustable gastric banding system cannot be placed laparoscopically, and you would rather have the procedure aborted rather than proceed with open surgical placement, please notify your surgeon pre-operatively.

Your signature below certifies that:

1) You have read the contents of this form, discussed the above verbally with the staff and have been given the opportunity to discuss it verbally with the surgeon, and understood the risks, benefits, and alternatives involved and hereby give INFORMED consent to proceed with LAPAROSCOPIC, POSSIBLE OPEN ADJUSTABLE GASTRIC BANDING SYSTEM PLACEMENT.

2) You pledge to cooperate with recommended guidelines for eating and for follow-up with the physician(s).

3) You agree to keep your surgeon informed of your address and phone number, and to participate in regular follow-up.

4) If your physician was not physically present when the consent form was witnessed by our staff you have the ability to reschedule an appointment with the physician, otherwise the physician will next meet you in the health care facility on the day of your surgery to ensure you have no final questions before proceeding with surgery.

Signature of Patient and Date:

Printed Name:

Signature of Witness and Date:

Printed Name:

Signature of Physician and Date:

Patient True / False Quiz

Please take this self-quiz before you make any further steps toward surgery. Understanding what will happen after surgery and what you must do to be successful is the most important step of the entire process. Please ask us if you have any doubts or questions about any of these or other issues:

		TRUE	FALSE
1	Staple or suture lines never leak, resulting in infection or communication between the stomach or intestine and the skin and erosion and slippage never occur in LAP-BAND cases.		
2	After surgery, I will be able to eat anything I want and as much as I want.		
3	Diabetes, high blood pressure, back pain and similar ailments always get better after obesity surgery.		
4	It is possible I will have more emotional difficulties after surgery because of the many ups and downs and changes my body and my relationships and interactions with the public will go through.		
5	Re-operation is sometimes necessary due to bleeding, hernias, ulceration, bursting of stitches or staples, leakage, blockage of the intestines or stomach, erosion or slippage, port problems, port or tubing leakage and other causes in LAP-BAND cases.		
6	I can still drink 2-3 cans of soda or carbonated juices, water or other beverages after my surgery, as long as it is in moderation.		
7	This operation for obesity will require routine visits with my surgeon for the first year, and then I will be okay on my own once I lose my weight and change my diet.		
8	Having Bariatric surgery will melt pounds off of me without lifestyle changes of dietary and exercise, since those things have not helped in the past.		
9	It is not necessary that I continue vitamins once I learn a proper diet after surgery.		
10	Once I lose my weight, I can drink as much alcohol as I want, as long as it is in moderation.		
11	There are complications and risks that I should discuss with the surgical team, and weight loss and surgical outcomes are not guaranteed.		
12	If I get the LAP-BAND procedure, I can have an adjustment to have the band opened more to eat more for a special occasion, like a wedding.		

Patient Name: _____

Date: _____

Answers to Patient Self-Quiz

1. False: Such events can occur and you should discuss them with the surgical team prior to surgery.
2. False: Successful surgery depends more upon YOU than any other aspect of this process. Diet is as important after surgery as the surgery itself.
3. False: Many such conditions are improved or resolve after surgery, but not always and not instantly. Your self care will play a key factor in your success with all of your symptoms.
4. True: This is very true and you should talk to our surgical team, psychologist, and other patients to assure you have a good understanding of what to expect after surgery.
5. True: This should be discussed with our surgical team prior to surgery.
6. False: You should not drink carbonated beverages of any kind right after surgery. Read the packet handouts and discuss the reasons for this with our surgical team. It is extremely important.
7. False: You will need to follow up at least annually with our surgical team, even after your first year of surgery.
8. False: Surgery is only ONE TOOL in your self-care plan. This is not an instant fix or miracle. YOU are in the driver's seat and must make the necessary lifestyle changes, and maintain them, in order for surgery to help you.
9. False: Gastric Bypass patients must continue to take vitamins for the remainder of their life. Some LAP-BAND patients stop taking vitamins after some time, after consulting our surgical team.
10. False: Your body will react differently to alcohol after surgery. Also, if you stick to the food intake required, drinking alcohol will use calories you need for nutritional foods instead. Discuss this with our surgical team.
11. True: Keep a list of all of your questions and concerns and discuss them with us at your appointments.
12. False: LAP-BANDs are never adjusted for someone to eat more voluntarily. Bands can be adjusted to allow for more food consumption during pregnancy. Otherwise, adjustments are for medical reasons only, not for patient desire to eat more without medical justification.

ASMBS BARIATRIC SURGERY CENTERS OF EXCELLENCE

**BARIATRIC OUTCOMES LONGITUDINAL DATABASE (“BOLD”)
INFORMED CONSENT DOCUMENT**

This is NOT the consent for your surgery

Title of Research Study: Bariatric Outcomes Longitudinal Database (BOLD)

Surgeon: _____

Hospital: _____

Principal Investigator: Walter J. Pories, M.D.

Research Institution: Brody School of Medicine
 East Carolina University
 600 Moye Boulevard
 Greenville, NC 27834

Data Coordinating Center: Surgical Review Corporation
 4800 Falls of Neuse Road, Suite 160
 Raleigh, NC 27609

INTRODUCTION

You have been asked to take part in a research study being conducted by East Carolina University and Surgical Review Corporation. The study is about bariatric (weight-loss) surgery. Before agreeing to take part in the study, it is important that you read and understand the following information regarding the study. Taking part in the research study is voluntary. If you decide not to take part in the study you will not be penalized or lose any benefits. You can still have weight-loss surgery. You may stop taking part in the study at any time without penalty.

This consent form may contain words that you do not understand. You should ask your surgeon or coordinator to explain any words or information in this consent form that you do not understand.

PURPOSE OF THE STUDY

The weight-loss surgery itself is not part of the study. It will be performed in the same way whether or not you agree to take part in the study.

The purpose of this study is to record and compare the long term results and effects of several types of weight-loss surgery. By comparing the type of surgery performed and the health of patients for five years after their surgery, we hope to learn:

- what types of patients do best after surgery
- the types of surgery that are most helpful, and
- which types of surgeries remain most helpful after five years.

Because you intend to have weight-loss surgery, we would like your surgeon to send us information about your medical condition and your surgery and to send us information about your health and weight loss each year for five years following your surgery.

PARTICIPANTS IN THE STUDY

- All patients who are having weight-loss surgery performed at an American Society for Metabolic and Bariatric Surgery (ASMBS) Bariatric Surgery Center of Excellence, including centers which have received Provisional Status designation, will be asked to take part in the study.
- All patients having surgery performed by a surgeon who is a Fellow of the ASMBS will be asked to take part in this study whether or not the surgery is performed at an ASMBS Bariatric Surgery Center of Excellence.

PERSONS CONDUCTING THE STUDY

Your weight-loss surgeon will send personal health information about you to Surgical Review Corporation, which works with East Carolina University to conduct the research.

PLAN AND PROCEDURES

If you choose to take part in this study, your surgeon will send health information about you to Surgical Review Corporation. Information sent will include:

- your name
- your date of birth
- your height
- your weight
- any prior surgeries
- the date of hospital admission and date of discharge for your weight-loss surgery
- the type of weight-loss surgery performed
- your medical condition before, during and immediately after the surgery
- your health condition and weight following your surgery each year for five years following your weight-loss surgery.

In the future, the researchers may ask you to take part in other research studies about weight and weight-loss surgery. You do not have to take part in these studies unless you want to. You can take part in future studies at the same time that you are taking part in this study.

If you decide not to have weight-loss surgery, or if the surgery does not occur for other reasons, you will no longer be part of this research study.

If you decide not to take part in the study, we will collect your age, gender, race, ethnicity, height and weight in a manner that cannot be traced back to you in order to have a record of the general medical condition of the people who have been asked but decided not to take part.

POTENTIAL RISKS AND DISCOMFORTS OF PARTICIPATING

There are no risks of physical harm associated with participating in the BOLD research study. The study does involve possible inconvenience in reporting your medical condition. There is a small risk of emotional distress in the event your medical information is inadvertently disclosed to unauthorized third parties.

POTENTIAL BENEFITS OF PARTICIPATING

Participation in the BOLD research study is not expected to provide any direct benefits to you. We hope the information and knowledge gained from the study will help surgeons improve the way the surgery is done and better understand the risks and benefits of each type of weight-loss surgery.

PRIVACY AND CONFIDENTIALITY OF RECORDS

As part of this study, identifiable health information or protected health information ("PHI") about you will be collected and used. The PHI will include demographic information (including your name, date of birth, gender, ethnicity and race), your medical history including prior surgeries and medical conditions, information regarding your weight loss surgery, and information regarding your medical condition following your surgery. Although your name will be collected, it will not be disclosed to the researchers and will only be accessed when necessary in order to identify you if you change surgeons or doctors.

By signing this consent form, you are authorizing the Principal Investigator and his employees and agents, employees and researchers at Surgical Review Corporation, and researchers at East Carolina University working with Surgical Review Corporation on this study to use your PHI in connection with this research study and to further disclose your PHI to representatives of the Institutional Review Board of East Carolina University, representatives of the Institutional Review Board or Research Compliance Office affiliated with your surgeon or hospital, agents of the U.S. Food and Drug Administration or other U. S. Government agencies, and other authorized persons.

If results from this research study are published, you will not be identified by name.

COSTS OF THE WEIGHT-LOSS SURGERY

You or your insurance company will be billed for all costs of the weight-loss surgery. We assume no obligation to pay any money or provide free medical care for your surgery or for any complications which may result from your surgery.

COSTS OF PARTICIPATION IN THE RESEARCH STUDY

There are no costs to you or your insurance provider for participating in the BOLD research study. No medical or surgical procedures or tests are performed as part of the study.

COMPENSATION FOR PARTICIPATING IN THE RESEARCH STUDY

You will not be paid for participating in the BOLD research study. We assume no obligation to pay any money or provide free medical care in case this research study results in any harm to you.

VOLUNTARY PARTICIPATION

Participating in this study is voluntary. You do not have to take part in this study in order to have weight-loss surgery. If you decide not to be in this study or decide to stop participating after it has already started, you may stop at any time without penalty. Your decision not to take part will not affect your medical care in any way.

You have the right to change your mind about permitting us access to your personal health information. If you decide to take away this permission you must notify your surgeon in writing. Any information collected up to the time you take away your permission may still be used. Deciding to no longer allow your information to be used in the study will not result in any penalty or loss to you.

WITHDRAWING YOUR PERMISSION

You may choose to withdraw this Consent as provided under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) at any time after you have signed it by providing your surgeon with a written statement that you wish to withdraw this Consent. Your withdrawal of this Consent will be effective immediately and your protected health information can no longer be used or disclosed for research purposes, except to the extent your surgeon or we have already taken action in reliance on your consent. In addition, your protected health information received before you withdrew consent may continue to be used or disclosed in order to preserve the integrity of an ongoing study.

[continued]

PERSONS TO CONTACT WITH QUESTIONS

The local investigator Dr. Ron Hekier will be available to answer any questions concerning this research, now or in the future. You may contact him at 903-794-0022 which is a daytime and nighttime phone number.

If you have additional questions, you may contact the Principal Investigator, Surgical Review Corporation, toll free at 866-746-0646. If you have questions about your rights as a research subject, you may call the Chair of the University and Medical Center Institutional Review Board at phone number 252-744-2914 (days) and/or the ECU Brody School of Medicine Risk Management Office at 252-744-2380 (days)

CONSENT TO PARTICIPATE

Title of research study: Bariatric Outcomes Longitudinal Database (BOLD)

I have read all of the above information. This study has been explained to me. I volunteer to take part in this research study. I have had a chance to ask questions, and I have received satisfactory answers to questions regarding areas I did not understand. I give permission to use my medical information as described in this consent form. (A copy of this signed and dated consent form will be given to the person signing this form as the participant or as the participant's authorized representative.)

Participant's Name **(PRINT)**

Signature

Date

Guardian's Name **(PRINT)**

Signature

Date

PERSON ADMINISTERING CONSENT: I have conducted the consent process and orally reviewed the contents of the consent document. I believe the participant understands the research.

Person Obtaining consent **(PRINT Name)**

Signature

Date