

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: Amir Moazzez, M.D.

Hospital: Inova Fair Oaks 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.

PERSONS TO CONTACT WITH QUESTIONS

The local investigator (your surgeon or designee) will be available to answer any questions concerning this research, now or in the future. You may contact your surgeon, Osvaldo Anez, MD, at phone numbers 703-860-8101(days) or (nights and weekends). 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 If applicable: (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)** _____

Signature **Date**